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9 **UNITED STATES DISTRICT COURT**
10 **CENTRAL DISTRICT OF CALIFORNIA**
11 **WESTERN DIVISION**

12 NATHANIEL L. ANDERSON,
Individually and on Behalf of All
13 Others Similarly Situated,

14 Plaintiff,

15 v.

16 PEREGRINE PHARMACEUTICALS,
INC., STEVEN W.KING, PAUL J.
17 LYTLE, JOSEPH S. SHAN and
18 ROBERT L. GARNICK,

19 Defendants.

Case No. SACV12-01647 PSG (FMOx)

CLASS ACTION

SECOND AMENDED COMPLAINT

1 that they bind to the same epitope. An epitope is a molecular region on the surface
2 of an antigen capable of eliciting an immune response and of combining with the
3 specific antibody produced by such a response.

4 4. It is possible to produce monoclonal antibodies that specifically bind to
5 almost any substance. Monoclonal antibodies can then serve to detect or purify that
6 substance. This has become an important tool in biochemistry, molecular biology
7 and medicine. When used as medications, the non-proprietary drug name ends in –
8 mab.

9 5. An issue involving the therapeutic use of monoclonal antibodies in
10 medicine was that initial methods used to produce them yielded mouse, not human
11 antibodies. While structurally similar, differences between the two were sufficient
12 to invoke an immune response when mouse monoclonal antibodies were injected
13 into humans, resulting in their rapid removal from the blood, as well as systemic
14 inflammatory effects, and the production of human anti-mouse antibodies
15 (“HAMA”).

16 6. To avoid the immune response, approaches using recombinant DNA
17 were developed. In one approach, mouse DNA encoding the binding portion of a
18 monoclonal antibody was merged with human antibody-producing DNA in living
19 cells. The expression of this “chimeric” DNA through cell culture yielded partially
20 mouse, partially human monoclonal antibodies. The descriptive term “chimeric”
21 monoclonal antibody has been used to reflect the combination of mouse and human
22 DNA sources used in the recombinant process. A chimeric antibody is named after
23 a chimera, the Greek mythological fire-breathing female monster, with a lion’s head,
24 a goat’s body, and a serpent’s tail.

25 7. Many chimeric protein drugs are monoclonal antibodies whose
26 specificity for a target molecule was developed using mice and hence were initially
27 “mouse” antibodies. The chimerization process involves engineering the
28 replacement of segments of the antibody molecule that distinguish it from a human

1 antibody. For example, human constant domains can be introduced, thereby
2 eliminating most of the potentially immunogenic portions of the drug without
3 altering its specificity for the intended therapeutic target. Antibody nomenclature
4 indicates this type of modification by inserting -xi- into the non-proprietary name
5 (e.g., abci-xi-mab). Hence “bavituximab.”

6 8. Even with chimeric antibodies that combine mouse and human DNA,
7 the body will create new antibodies that target the chimeric antibody. These new
8 antibodies are known as human anti-chimeric antibodies (“HACA”).

9 9. The Phase II clinical trial in issue was named the “Study of
10 Bavituximab Plus Docetaxel in Patients With Locally Advanced or Metastatic Non-
11 Squamous Non-Small Cell Lung Cancer” (hereinafter, the “Phase II Trial”). The
12 Phase II Trial enrolled 121 patients (117 evaluable per the study protocol) with
13 second-line non-squamous NSCLC following one prior chemotherapy regimen at
14 over 40 clinical centers. Patients were equally randomized to 1 of the 3 treatment
15 arms, docetaxel (75mg/m²) plus either placebo, 1 mg/kg bavituximab, or 3 mg/kg
16 bavituximab until disease progression.

17 10. The Phase II Trial was supposed to be double-blinded, meaning that
18 each patient received a code number which concealed from Peregrine, the clinical
19 investigators and the patients whether they were assigned to receive placebo, 1 mg
20 or 3 mg of bavituximab. Approximately 50% of the patients were enrolled in the
21 United States and 50% were enrolled internationally with equal distribution between
22 all treatment groups.

23 11. Throughout the Class Period, Defendants violated the Exchange Act by
24 disseminating materially false and misleading statements to the investing public
25 about the effectiveness of the Company’s experimental drug bavituximab as a
26 treatment for NSCLC, making it impossible for shareholders to gain a meaningful or
27 realistic understanding of the drug’s prospects. As a result of Defendants’ materially
28 false and misleading statements, Peregrine’s securities traded at artificially inflated

1 prices during the Class Period, reaching a high of \$5.39 per share on September 21,
2 2012.

3 12. This case is about the Phase II Trial which was the most important
4 clinical trial in the history of Peregrine. The purpose of the Phase II Trial was to
5 determine if reliable scientific data could be obtained, indicating that bavituximab
6 was more efficacious than placebo in a test group of 117 cancer patients. When the
7 Phase II Trial was unblinded on May 21, 2012, Peregrine, as the Sponsor of the
8 Phase II Trial, had unfettered access to all the data generated, including the
9 previously collected patient blood samples. A routine P-K test (described below) of
10 the patient blood confirms whether the patient received bavituximab or placebo.
11 Whether the patient received bavituximab or placebo is the necessary and crucial
12 first step in confirming that all the other data generated by the Phase II Trial was
13 accurate and reliable.

14 13. On May 21, 2012, once the Phase II Trial was unblinded, Defendants
15 began to immediately tout that the Phase II Trial demonstrated bavituximab was
16 better than placebo. Defendants began to tout the results of the Phase II Trial as true
17 and accurate but failed to disclose to the market that they had not even verified
18 through P-K testing of the collected patient blood samples that the patients
19 designated to receive placebo and bavituximab had in fact correctly received the
20 assigned substance. This was a material omission actionable under the securities
21 laws.

22 14. Defendants also violated the securities laws by touting the Phase II
23 Trial results as positive when they had actual knowledge that they had not verified
24 whether the patients received the designated substance and thus they actually knew
25 they did not know whether the Phase II Trial results they were touting were accurate
26 or false.

27 15. Then, suddenly, on September 24, 2012, after four months of touting
28 the data as positive, Peregrine issued a press release warning of “major

1 discrepancies” in the results of the Phase II Trial and advising investors that they
2 should not rely on the “clinical data” the Company had previously disclosed from
3 September 7, 2012 and earlier as to the Phase II Trial. Peregrine blamed the “major
4 discrepancies” on a third-party vendor who worked on the Phase II Trial prior to its
5 unblinding. As described *infra*, that third-party vendor has specifically denied
6 Peregrine’s accusations.

7 16. On this news, Peregrine’s stock plummeted \$4.23 per share to close at
8 \$1.16 per share on September 24, 2012, a one-day decline of 78%.

9 17. On September 26, 2012, Peregrine filed a Form 8-K with the SEC,
10 which disclosed that the Company had received on September 24, 2012 (the same
11 day Peregrine issued its press release announcing “major discrepancies” in the
12 results of the Phase II Trial) a written notice of default from Oxford Finance LLC
13 (“Oxford”), Silicon Valley Bank (“SVB”) and MidCap Financial SBIC, LP
14 (“MidCap”) (collectively, the “Oxford Group Lenders”), with respect to a security
15 agreement the Company had entered into on August 30, 2012. According to the
16 Company, the lender deemed the Company’s disclosure on September 24, 2012,
17 concerning the “major discrepancies” in the results from its Phase II Trial to be a
18 material adverse change under the terms of the loan agreement and, as result, the
19 Oxford Group Lenders accelerated the repayment of the loan and demanded
20 repayment in full for the outstanding amounts.

21 18. On this news, Peregrine’s stock declined \$0.55 per share to close at
22 \$1.11 per share on September 27, 2012, a one-day decline of 33%.

23 19. Defendants *admit* that they knew that the interim data regarding the
24 Phase II Trial was false and misleading by no later than *on or about* September 20,
25 2012. See Complaint for Breach of Contract and Negligence; Demand for Jury
26 Trial, *Peregrine Pharmaceuticals, Inc. v. Clinical Supplies Mgmt.*, C.D. Cal. Civil
27 Action No.: 12-cv-01608-JGB-AN (“*Peregrine v. CSM*”) (Dkt. No. 1) at ¶ 10.

28

1 20. As a result of Defendants' materially false and misleading statements,
2 Peregrine securities traded at artificially inflated levels during the Class Period.
3 However, after the above revelations were revealed to the market, the Company's
4 securities dropped precipitously.

5 **JURISDICTION AND VENUE**

6 21. The claims asserted herein arise under and pursuant to Sections 10(b)
7 and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10(b)-5
8 promulgated thereunder (17 C.F.R. § 240.10b-5).

9 22. This Court has jurisdiction over the subject matter of this action
10 pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa), and 28 U.S.C.
11 § 1331.

12 23. Venue is proper in this Judicial District pursuant to Section 27 of the
13 Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b). Many of the acts and
14 transactions alleged herein, including the preparation and dissemination of
15 materially false and misleading information, occurred in substantial part in this
16 Judicial District.

17 24. In connection with the acts, conduct and other wrongs alleged in this
18 Complaint, Defendants, directly or indirectly, used the means and instrumentalities
19 of interstate commerce, including but not limited to, the United States mails,
20 interstate telephone communications and the facilities of the national securities
21 exchange.

22 **PARTIES**

23 25. Lead Plaintiff James T. Fahey ("Plaintiff"), as set forth in the attached
24 certification, purchased Peregrine securities at artificially inflated prices during the
25 Class Period and has been damaged as a result of the revelations by Defendants of
26 their prior false statements and material omissions.

27 26. *Defendant Peregrine*, as stated *supra*, is a clinical-stage
28 biopharmaceutical company that develops and manufactures monoclonal antibodies

1 for the potential treatment of cancer and viral infections. Peregrine's key product is
2 bavituximab, a phosphatidylserine targeting antibody. Peregrine is studying
3 bavituximab as a primary (front-line) and second-line treatment for NSCLC and
4 other cancers.

5 27. **Defendant Stephen W. King** ("King") is, and at all relevant times was,
6 the Company's Chief Executive Officer ("CEO"), President and a Director.
7 Pursuant to the Company DEF 14A filed with the SEC on August 27, 2012,
8 Defendant King owned 703,325 shares of Peregrine securities. *See* Peregrine's DEF
9 14A, filed with the SEC August 27, 2012 at p. 19. Further, pursuant to the
10 Company's DEF 14A, filed with the SEC on August 26, 2013, Defendant King had
11 increased his ownership to 1,224,340 shares of Peregrine securities. *Id.* at p. 20.

12 28. **Defendant Paul J. Lytle** ("Lytle") is, and at all relevant times was, the
13 Company's Chief Financial Officer ("CFO"). Pursuant to the Company DEF 14A
14 filed with the SEC on August 27, 2012, Defendant Lytle owned 374,557 shares of
15 Peregrine securities. *See* Peregrine's DEF 14A, filed with the SEC on August 27,
16 2012 at p. 19. Further, pursuant to the Company's DEF 14A, filed with the SEC on
17 August 26, 2013, Defendant Lytle had increased his ownership to 638,991 shares of
18 Peregrine securities. *Id.* at p. 20.

19 29. **Defendant Joseph S. Shan** ("Shan") is, and at all relevant times was,
20 the Company's Vice President, Clinical and Regulatory Affairs. Pursuant to the
21 Company DEF 14A filed with the SEC on August 27, 2012, Defendant Shan owned
22 221,936 shares of Peregrine securities. *See* Peregrine's DEF 14A, filed with the
23 SEC on August 27, 2012 at p. 19. Further, pursuant to the Company's DEF 14A,
24 filed with the SEC on August 26, 2013, Defendant Shan had increased his ownership
25 to 422,936 shares of Peregrine securities. *Id.* at p. 20.

26 30. **Defendant Robert L. Garnick** ("Garnick") is, and at all relevant times
27 was, the Head of Regulatory Affairs.
28

1 31. Defendants named above in ¶¶ 27-30 are referred to herein as the
2 “Individual Defendants.”

3 **BACKGROUND**

4 **A. The Company Background**

5 32. The drug bavituximab, given by intravenous infusion, is a genetically
6 engineered antibody designed to target a lipid molecule found on tumor blood
7 vessels that acts to suppress the body’s immune system.

8 33. The antibody binds to the targeted molecule to reactivate “the immune
9 response locally at the site of the tumor,” allowing the immune system to combat
10 cancer cells, stated Defendant Shan, head of clinical and regulatory affairs at
11 Peregrine. *See* Peregrine’s Form 10-K for year ended April 30, 2010 (“2010 Form
12 10-K”).

13 34. Peregrine stated in its public statements to investors that lung cancer is
14 the second most commonly diagnosed cancer with 219,440 new cases and 159,000
15 deaths in 2009 in the United States alone.

16 35. Peregrine also stated in its public statements to investors that NSCLC is
17 the most common type of lung cancer accounting for approximately 85% to 90% of
18 all lung cancers.

19 36. NSCLC is any type of epithelial lung cancer other than small cell lung
20 carcinoma (“SCLC”). As a class, NSCLCs are relatively resistant to chemotherapy,
21 compared to small cell carcinoma.

22 37. Peregrine stated in its public statements to investors that the five (5)
23 year survival for NSCLC patients is only 1%.

24 38. Peregrine has attempted to develop bavituximab as a therapeutic agent
25 against various types of cancer for many years. As of fiscal year ended 2012,
26 Peregrine was engaged in at least seven (7) clinical trials in Phase I and Phase II
27 attempting to test whether bavituximab was efficacious against five (5) different
28 types of cancer: NSCLC, pancreatic, liver, prostate, and breast.

1 39. Clinical development of bavituximab for the treatment of cancer began
2 in 2008. Since that time, Peregrine has conducted at least twelve (12) Phase-I/-II
3 studies and treated 613 cancer patients, but has yet to observe a statistically
4 significant improvement over a contemporary standard-of-care (“SOC”).

5 40. As of April 30, 2012, Peregrine’s only other potential product which
6 had advanced through a Phase II Trial, was a second agent called Cotera. Peregrine
7 is attempting to develop Cotera as a single treatment brain cancer therapy. Peregrine
8 has conducted at least four (4) clinical trials and claims that “Cotera has
9 demonstrated encouraging survival, localization to the tumor, and an acceptable
10 safety profile in patients with brain cancer.” *See* Form 10-K for year ended April
11 30, 2012 (“2012 Form 10-K”) at p. 8. Despite the fact that Cotera has been granted
12 Food and Drug Administration (“FDA”) and European Medicines Agency (“EMA”)
13 orphan drug status for glioblastoma multiforme (“GBM”) and anaplastic
14 astrocytoma, and fast track designation in the U.S. for the treatment of recurrent
15 GBM, Peregrine has been unable to develop Cotera as a commercial drug. Orphan
16 drug status refers to a pharmaceutical agent that has been developed specifically to
17 treat a rare medical condition. Even if Peregrine was able to commercially develop
18 Cotera, the market for the drug is small. According to Peregrine, there will be only
19 an estimated 22,900 malignant brain tumors diagnosed in 2012 of which only 15%
20 are GMB (approximately 3,435). Accordingly, any profits that may ultimately been
21 achieved from Cotera will not be enough to ensure the survival of Peregrine – only
22 the commercial development of bavituximab can do that.

23 41. Peregrine has not made a profit in its last eight (8) years of existence
24 and, upon information and belief, has never made a profit during its entire existence.

25 42. For its past eight (8) fiscal years, Peregrine has operated at a net loss:

- 26 (a) As of April 30, 2005, Peregrine had a net loss of \$15,452,000;
- 27 (b) As of April 30, 2006, Peregrine had a net loss of \$17,061,000;
- 28 (c) As of April 30, 2007, Peregrine had a net loss of \$20,796,000;

- (d) As of April 30, 2008, Peregrine had a net loss of \$23,176,000;
- (e) As of April 30, 2009, Peregrine had a net loss of \$16,524,000;
- (f) As of April 30, 2010, Peregrine had a net loss of \$14,494,000;
- (g) As of April 30, 2011, Peregrine had a net loss of \$34,151,000;
- (h) As of April 30, 2012, Peregrine had a net loss of \$42,119,000;
- and
- (i) As of April 30, 2013, Peregrine had a net loss of \$29,780,000;

43. Peregrine's only way to finance its operations, which consistently run at a loss, is to either borrow money from lenders or to issue stock into the public markets.

44. In recent years, Peregrine has only been able to borrow money from lenders in two (2) instances.

45. The first such loan was on or about December 9, 2008, when Peregrine entered into a loan and security agreement with MidCap Financial, LLC and BlueCrest Capital Finance, LP to borrow \$10 million. Peregrine received initial funding of \$5 million under the loan and security agreement.

46. Peregrine repaid this loan in full by December 2011 through Company stock sold into the public markets.

47. Peregrine's second loan transaction was with the Oxford Group Lenders on or about August 30, 2012. This loan provided for up to \$30 million in total funding available in two (2) tranches of \$15 million. Peregrine took the first \$15 million in funding available on or about August 30, 2012.

48. Peregrine was able to secure the first tranche (\$15 million) as a result of the false and misleading statements issued to the market during the Class Period.

49. Peregrine represented to the public that, at its option, it could draw down the second \$15 million tranche, "if, on or before March 31, 2013, we (i) achieve positive overall survival data in our bavituximab Phase II second-line non small cell lung cancer ('NSCLC') clinical trial and (ii) have a positive end of Phase

II meeting with the U.S. Food and Drug Administration (‘FDA’) regarding our bavituximab second-line NSCLC clinical trial (defined as our ability to move into a Phase III trial design) (the ‘End of Phase II Event’).” *See* Form 10-Q for period ending July 31, 2013 (“2Q 2012 Form 10-Q”) at p. 12.

50. The only other method for Peregrine to raise money to fund its operations and cover its net losses was to sell Company stock into the public markets. Peregrine did this by making several shelf registrations of its common stock and entering into At Market Sales Issuance Agreements (“AIMs”) whereby its agents consistently sold Peregrine’s stock into the market, thereby raising funds but, each time, diluting the ownership interest of existing shareholders.

51. From 2007 to the present, Peregrine sold its stock into the market, raising in excess of \$335 million, and each time diluting shareholder value.

52. Some of Peregrine’s motives for being deliberately reckless in touting the so-called positive nature of the data from the bavituximab Phase II Trial were to obtain loans to show the public it was credit-worthy and be able to raise more money through stock sales to the market but to do so at higher, artificially inflated prices so that less stock would have to be sold to raise the target amount of money and thus causing less dilution of the Individual Defendants’ ownership interests.

53. Peregrine previously admitted that it does not have the technology, capacity or the money to bring bavituximab into a Phase III clinical trial by itself, though it is nonetheless presently attempting to conduct a Phase III trial on its own, having failed to attract any partners to joint venture with it.

54. If Peregrine is unable to successfully bring bavituximab through a Phase III clinical trial and receive FDA approval to sell it as a commercial drug, either alone or with a partner, Peregrine will fail as a company.

B. Phase I Through III

55. In order to market a drug in the United States, developers must first obtain the approval of the FDA. This approval process includes, among other

1 required research, conducting a series of clinical trials to establish the safety and
2 efficacy of the drug. The maker of the drug then submits the clinical results of these
3 trials to the FDA to satisfy the safety and efficacy of the new drug as part of its New
4 Drug Application (“NDA”):

- 5 • **Phase I** trials test the safety, dose tolerance, and other
6 pharmacokinetic/bioavailability properties of the drug. Phase I trials
7 also identify the primary side-effects, if any, that the drug may cause.
- 8 • In **Phase II** trials, researchers test the drug in a patient population to
9 gather information about efficacy, optimal dosage levels, adverse
10 effects, and safety risks versus the benefits. Phase II studies are
11 conducted in a significant patient population designed to assess the
12 most effective and safe dose that will be evaluated in a Phase III study.
13 During the clinical development of a new drug, the results of a Phase II
14 study will determine if a drug is safe and effective to administer in a
15 larger patient population. A Phase II study is critical in the new drug
16 development process. If the risks outweigh the benefits and the patient
17 safety is severely jeopardized during the Phase II study, the research on
18 that drug is almost always stopped. The FDA will approve a drug that
19 demonstrated sufficient data to show the most effective dose correlated
20 with the safety profile. This is established in the Phase II program and
21 will be the dose selected to be evaluated in the Phase III study.
- 22 • **Phase III** trials test the efficacy and safety of the drug in an expanded
23 patient population at geographically dispersed trial sites. The results of
24 the Phase III program must demonstrate that the drug is statistically
25 significantly better than the current standard of care.

1 **C. Pharmacokinetic (“P-K”) Testing**

2 56. Pharmacokinetics is the process by which a drug is absorbed,
3 distributed, metabolized and eliminated by the body. Pharmacokinetics is also the
4 study of this process.

5 57. Peregrine developed a pharmacokinetics test, called a P-K test,
6 specifically designed to reveal the presence of bavituximab in a patient’s blood
7 sample and to study how bavituximab is absorbed, distributed, metabolized and
8 eliminated by the body.

9 58. As demonstrated by CW3 (¶ 130), CW10 (¶ 185, 186), CW11 (¶¶ 196,
10 201), CW17 (¶¶ 105), CW20 (¶ 96), Peregrine had possession and control over all
11 patient blood samples drawn during the course of the Phase II Trial.

12 59. Once the Phase II Trial was unblinded on May 21, 2012, Peregrine had
13 the ability to test blood samples at very little cost (*see, e.g.*, CW9 (¶ 168), CW10 (¶¶
14 183, 187), CW11 (¶¶ 63, 201), CW15 (¶ 103)) of all 117 patients involved in the
15 Phase II Trial, and know, based on their unblinded identification code, which
16 patients were supposed to have received placebo, which patients were supposed to
17 have received 1 mg dosages of bavituxmiab and which patients were supposed to
18 have received 3 mg dosages of bavituximab. *See, e.g., id.*

19 60. Confidential Witness No. 11 (“CW11”) is, for example, a former
20 Peregrine employee and was a Research Associate in the Process Sciences
21 department at Peregrine, charged with research and development (“R&D”). CW11
22 left Peregrine in approximately November of 2012. As a Research Associate with
23 the Process Sciences department, CW11 has personal knowledge regarding the
24 Phase II Trial.

25 61. CW11 has the skills and actual personal experience in the conducting of
26 Peregrine’s P-K test to detect the presence of bavituximab in a patient’s blood
27 sample.

1 62. CW11 stated that a P-K test is an ELISA based assay. The
2 enzyme-linked immunosorbent assay (“ELISA”) is a test that uses antibodies and
3 color change to identify a substance. ELISA is a popular format of a wet-lab type of
4 analytic biochemistry assay that uses a solid-phase enzyme immunoassay (“EIA”) to
5 detect the presence of a substance, usually an antigen, in a liquid sample or wet
6 sample. In the ELISA based assay, antigens from the sample are attached to a
7 surface. Then, a further specific antibody is applied over the surface so it can bind
8 to the antigen. This antibody is linked to an enzyme, and, in the final step, a
9 substance containing the enzyme’s substrate is added. The subsequent reaction
10 produces a detectable signal, most commonly a color change in the substrate.

11 63. CW11 stated that Peregrine’s P-K test, which detects the presence of
12 bavituximab, takes five (5) to six (6) hours to perform, and is relatively inexpensive
13 to perform. CW11 also stated that as many as ten (10) different patient blood
14 samples can be applied to the plate on which the test is performed and that a research
15 scientist such as himself/herself could, and does, easily simultaneously monitor at
16 least four (4) plates with ten different patient blood samples per plate.

17 64. Four (4) plates times ten (10) different patient blood samples per plate
18 equals forty (40) different patient samples. Thus, three (3) research scientists could
19 test the entirety of the 117 patient cohort in the Phase II Trial for all three arms
20 (placebo, 1 mg of bavituximab and 3 mg of bavituximab) in five (5) to six (6) hours,
21 or one Peregrine research scientist could test all patients’ blood samples in fifteen
22 (15) to eighteen (18) hours.

23 65. Thus, according to CW11, as early as May 21, 2012 when the Phase II
24 Trial was unblinded, Peregrine had the ability to conduct a P-K test in less than one
25 (1) to two (2) days to confirm the presence or absence of bavituximab in patient
26 blood samples of every single patient in this Phase II Trial. *See also* CW9 (¶ 168),
27 CW10 (¶¶ 183, 187), CW15 (¶ 103).

28

D. Human Anti-Chimeric Antibodies (“HACA”) Test

66. Bavituximab is a monoclonal antibody, which was developed using mouse DNA and human DNA. Because the antibody contains the DNA of two different species, it is often referred to as a chimeric antibody.

67. When a chimeric antibody is administered to a human, the human’s blood often recognizes the substance as a foreign substance because the body detects the presence of the foreign DNA, in this case mouse DNA. When this happens, the body creates new antibodies in response to the presence of the foreign body.

68. Therefore, when bavituximab is given to patients, additional antibodies are often generated by the body. These new antibodies are called human anti-chimeric antibodies, abbreviated as HACA.

69. Peregrine possesses a test to detect the presence of HACA in a patient’s blood who has received bavituximab. *See, e.g.*, CW1 (¶ 124), CW3 (¶ 130), CW9 (¶ 166), CW10 (¶ 173, 175), CW20 (¶ 96). According to CW11, the HACA test is also an ELISA based test, a standard scientific test routinely conducted.

70. CW3, CW9, and CW10 stated that they were familiar with the HACA test used by Peregrine and CW3 and CW10 stated that it had been conducted on patient blood samples many times during their tenure with Peregrine. *See* ¶¶ 130, 173, 175. A patient who had received placebo should not have any HACA in his or her blood sample as a person assigned to receive placebo should not have received bavituximab containing mouse DNA and thus no HACA should have been generated in his/her blood in response.

71. Thus, as early as May 21, 2012, Peregrine had the ability to run two different types of test on patient blood, the HACA test and the P-K test. The HACA test would have immediately alerted them to the fact that placebo-designated patients had potentially received bavituximab in error because HACA would be present in a blood sample where they should not be and thus an immediate follow up investigation was warranted to determine if the study data was false. The P-K test

1 would have told Defendants that placebo designated patients had definitely received
 2 bavituximab in error because bavituximab was found in the placebo-designated
 3 patient's blood sample and thus the study data was definitely false.

4 **E. Icon Was The Central Laboratory for the Phase II Trial**

5 72. Confidential Witness No. 12 ("CW12") is the Medical Director of MB
 6 Quest in Moscow, Russia. CW12 stated that MB Quest was a Contract Research
 7 Organization ("CRO") for Peregrine for the Phase II Trial in issue. MB Quest was
 8 founded in Moscow in 1997 as one of the first international CROs to work in Russia.
 9 MB Quest provides sponsors such as Peregrine with a full range of clinical trial
 10 services in Russia, Ukraine, Belarus, Georgia, and Kazakhstan. A CRO is defined
 11 by Section 1.20 of E6 of the International Conference on Harmonisation ("ICH") on
 12 Good Clinical Practices as "a person or an organization (commercial, academic or
 13 other) contracted by the sponsor to perform one or more of a sponsor's trial-related
 14 duties and functions."

15 73. CW12 worked on the Phase II Trial in issue, and has personal
 16 knowledge regarding the Phase II Trial. CW12 stated that nurses at MB Quest
 17 collected the patient blood samples according to the Protocol, and sent the results of
 18 blood tests and the blood samples directly to the central laboratory, Icon.

19 **F. Defendants Admit That Reliance On Third Parties to Conduct Clinical**
 20 **Trials Do Not Relieve Them of Conducting, Monitoring, Recording and**
 21 **Reporting the Results of Clinical Trials to Ensure That the Data and**
 22 **Results Are Scientifically Credible and Accurate**

23 74. "Monitoring" is defined by Section 1.38 of E6 of the ICH on Good
 24 Clinical Practices as "the act of overseeing the progress of a clinical trial, and of
 25 ensuring that it is conducted, recorded, and reported in accordance with the protocol,
 26 Standard Operating Procedures ("SOPs"), Good Clinical Practice ("GCP"), and the
 27 applicable regulatory requirements."
 28

75. Defendants admit in their 2012 Form 10-K that, in the course of discovery, preclinical testing and clinical trials, the Company relies on third parties, including universities, investigators and clinical research organizations, to perform critical services for them. For example, the Company relies on third parties to conduct its clinical trials and many of its preclinical studies. Clinical research organizations and investigators are responsible for many aspects of the trials, including finding and enrolling patients for testing and administering the trials. Although the Company relies on these third parties to conduct its clinical trials, ***“the Company is responsible for ensuring that each of its clinical trials is conducted in accordance with its investigational plan and protocol.”*** (Emphasis added). “Protocol” is defined by Section 1.44 of E6 of the ICH on Good Clinical Practices as “a document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial.”

76. Moreover, the FDA and foreign regulatory authorities, including the ICH, require the Company to comply with regulations and standards, commonly referred to as ***Good Clinical Practice*** for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible, accurate and viable and that the trial subjects are adequately informed of the potential risks of participating in clinical trials via a signed Informed Consent (“IC”). ***The Company’s reliance on third parties does not relieve it of these responsibilities and requirements.*** “Good Clinical Practice” is defined by Section 1.24 of E6 of the ICH on Good Clinical Practices as “a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected.”

77. According to the Company’s SEC filings, Peregrine admits “[a] clinical trial must be conducted according to ***good clinical practice*** following protocols that

1 detail the trial's objectives, inclusion and exclusion criteria, the parameters to be
 2 used to monitor safety and the efficacy criteria to be evaluated, and informed
 3 consent must be obtained from all study subjects." *See* 2012 Form 10-K at p. 14
 4 (Emphasis added).

5 78. The Company's participation in conducting clinical research on a new
 6 drug makes Peregrine totally obligated to follow GCP as outlined in the Code of
 7 Federal Regulations, the European Directives and the ICH Guidelines. These
 8 regulations are specific and demand that all clinical research be conducted according
 9 to these regulations. Any conduct by investigators, their staffs, third parties who
 10 package and distribute the drug, statisticians, internal staff, all come under the
 11 responsible persons in charge of a company or their designees and must follow GCP.

12 79. It is up to the sponsor company (Peregrine) to monitor and ensure that
 13 every aspect of the clinical research development is conducted according to GCP.
 14 Any errors or omissions that occur during the clinical research development must be
 15 scrutinized and reported during the clinical trials. Distribution of study medication
 16 must have a complete accountability. Each study center must be monitored closely
 17 to guard against any protocol violations or mistakes in study drug administration to
 18 the patients participating in this study.

19 80. The Phase II Trial in issue was not properly administered and
 20 monitored by Defendants in violation of GCP.

21 **G. The Company Attempts to Divert the Attention Away from Its Deliberate**
 22 **Recklessness and Deviation from Good Clinical Practices and Places the**
 23 **Blame on Clinical Supplies Management, Inc.**

24 81. In order to divert attention from Defendants' deliberate recklessness in
 25 their failure to properly monitor, record, verify and report the results of the Phase II
 26 Trial, on September 24, 2012 (the *same day* the Company announced to the
 27 investors that it had discovered "major discrepancies" in the Phase II clinical data
 28

1 previously reported), the Company filed a suit against Clinical Supplies
2 Management, Inc. (“CSM”). *See Peregrine v. CSM* (Dkt. No. 1).

3 82. The reasonable inference is that Peregrine was aware of the “major
4 discrepancies” for many days or weeks enabling it time to retain counsel, discuss the
5 situation and have a complaint prepared, reviewed and filed in coordination with the
6 preparation and issuance of the September 24, 2012 press release.

7 83. CSM is a third party, independent, FDA-approved CRO that the
8 Company contracted with to execute treatment group assignments and oversee
9 clinical trial material coding and distribution in its second-line NSCLC double-
10 blinded trial.

11 84. The Company alleges in its complaint against CSM that “[o]n or about
12 September 20, 2012, Peregrine discovered major discrepancies between some
13 patient sample test results and patient treatment code assignments. CSM’s error(s)
14 call in to question the accuracy of the results noted and reported on September 7,
15 2012. While the scope of CSM’s error(s) is currently under review, its error(s) will
16 diminish the goodwill achieved from the trial results and require analysis and
17 evaluation presently under way and continuing. The magnitude of the resulting
18 harm is currently unknown.” *Peregrine v. CSM* (Dkt. No. 1) at ¶ 10.

19 85. On January 16, 2013 (only six days before the expiration of the 120
20 days provided for service under Fed. R. Civ. Proc. 4(m)), the Company served the
21 complaint on CSM. *See Id.* (Dkt. No. 7).

22 86. Shortly thereafter, on March 7, 2013, the Company and CSM entered
23 into a stipulation to stay the action (*see id.* (Dkt. No. 8)) because the Master Services
24 Agreement entered into between Peregrine and CSM, dated on or about March 18,
25 2010, required the parties to participate in a dispute resolution process in the event
26 of any controversy or claim arising out of, relating to or in connection with any
27 provision of said agreement, or the rights or obligations of the parties thereunder,
28 before pursuing their rights and remedies at law or equity.

1 87. Thus, there was no realistic chance that the Company's lawsuit against
 2 CSM could have proceeded without a prior participation in a dispute resolution
 3 process. Indeed, had the Company not been looking to divert attention away from
 4 its own misconduct, it could have simply initiated a dispute resolution process with
 5 CSM directly and without the publicity of the lawsuit.

6 88. On March 8, 2013, the Court in the *Peregrine v. CSM* lawsuit entered
 7 an order staying the proceedings for a period of 120 days from the entry of the Order
 8 to allow the parties to pursue the dispute resolution process. *See id.* (Dkt. No. 11).

9 89. On July 11, 2013, CSM answered Peregrine's complaint, denying any
 10 wrongdoing and making reference to "Change Orders" to the original contract which
 11 Peregrine had insisted upon receiving. *See Peregrine v. CSM* (Dkt. No. 13) (the
 12 "CSM Answer" at ¶¶ 4, 9). According to CSM's Answer, "Peregrine's alleged
 13 damages and losses, if any, were caused by its own actions or the actions of other
 14 parties or entities, which were not proximately caused by CSM" (CSM Answer at
 15 Eighth Affirmative Defense); "Peregrine consented to and approved the alleged acts
 16 for which it now complains. Accordingly, Peregrine is barred in whole or in part
 17 from pursuing this action." *Id.* at Ninth Affirmative Defense.

18 **CONFIDENTIAL WITNESSES**

19 90. Confidential Witness No. 16 ("CW16") was the physician in charge of
 20 the Phase II Trial at the investigator site in the county of Georgia, the City of Tbilissi
 21 and the clinic named Gvamichava. CW16 worked on the Phase II Trial in issue, and
 22 has personal knowledge regarding the Phase II Trial.

23 91. CW16 confirmed that patient blood was drawn on each patient visit and
 24 that general blood tests were performed at the investigator site.

25 92. CW16 also confirmed that blood samples were taken and sent to the
 26 central laboratory for further testing. CW16 confirmed that the central laboratory
 27 was Icon, located in Ireland.
 28

1 93. CW16 confirmed that MB Quest was Peregrine's representative in
2 Georgia. CW16 confirmed that MB Quest was a contract research organization for
3 Peregrine and acted as a monitor for Peregrine as to the European sites.

4 94. Confidential Witness No. 20 ("CW20") is a Director of MB Quest in
5 the country of Georgia. CW20 worked on the Phase II Trial in issue, and has
6 personal knowledge regarding the Phase II Trial.

7 95. CW20 confirmed that MB Quest managed the Phase II Trial in issue for
8 Peregrine at the European sites.

9 96. CW20 confirmed that MB Quest collected blood samples of the patients
10 and sent them to Peregrine who conducted the P-K and HACA tests themselves.

11 97. CW20 confirmed that they communicated with Peregrine using an SRS
12 electronic database platform and sent patient trial results to Peregrine via the SRS
13 electronic database platform.

14 98. Confidential Witness No. 13 ("CW13") is a nurse at the State Medical
15 Preventive Institution "Chelyabinsk Regional Clinical Oncology" in Chelyabinsk,
16 Russia. Chelyabinsk Regional Clinical Oncology is one of the investigator sites in
17 Russia. CW13 worked on the Phase II Trial in issue, and has personal knowledge
18 regarding the Phase II Trial.

19 99. CW13 confirmed that this investigator site took blood samples of the
20 Phase II Trial patients and sent them to the central laboratory, Icon.

21 100. Confidential Witness No. 14 ("CW14") is the Head of the
22 Chemotherapy Department at the State Medical Preventive Institution "Chelyabinsk
23 Regional Clinical Oncology" in Chelyabinsk, Russia. CW14 worked on the Phase II
24 Trial in issue and has personal knowledge regarding the Phase II Trial.

25 101. CW14 confirmed that this investigator site took blood samples of the
26 Phase II Trial patients and sent them to the central laboratory, Icon.

27 102. Confidential Witness No. 15 ("CW15") confirmed that he/she was the
28 physician responsible for conducting the Phase II Trial in issue in the country of

1 Ukraine at the Kharkiv investigator site known as State Institute, Institute of Medical
2 Radiology named after S.P. Grygoryev of AMS of Ukraine, Department of
3 Chemotherapy. CW15 worked on the Phase II Trial in issue, and has personal
4 knowledge regarding the Phase II Trial.

5 103. CW15 confirmed that his/her clinic received the vials of the placebo
6 and the bavituximab in a blinded and coded fashion and then sent the results of the
7 Phase II Trial -- organized by which patient received which coded substance -- to
8 Peregrine so that Peregrine could analyze the patient results once the Phase II Trial
9 was unblinded.

10 104. Confidential Witness No. 17 ("CW17") was the main Oncologist
11 working on the Phase II Trial in issue in the country of Georgia, in the city of
12 Tbilissi at the Medulla Chemotherapy and Immunotherapy clinic. CW17 worked
13 on the Phase II Trial in issue, and has personal knowledge regarding the Phase II
14 Trial.

15 105. CW17 confirmed that blood samples were drawn from the patients and
16 those blood samples were sent to Peregrine for P-K testing to be done by Peregrine.

17 106. Confidential Witness No. 18 ("CW18") was a nurse in the Oncology
18 Department at the investigator site at the State Institute of Healthcare, Ivanovo
19 Regional Oncology Dispensary in Ivanovo, Russia, responsible for the Phase II Trial
20 in issue. CW18 worked on the Phase II Trial in issue, and has personal knowledge
21 regarding the Phase II Trial.

22 107. CW18 confirmed that the physician and oncologist responsible for
23 conducting the Phase II Trial at the Ivanovo investigator site was Confidential
24 Witness No. 19 ("CW19").

25 108. CW19 worked on the Phase II Trial in issue, and has personal
26 knowledge regarding the Phase II Trial. CW19 confirmed that patient blood
27 samples were drawn every time the patient visited the investigator site. CW19
28

1 confirmed that blood tests were conducted at the investigator site and that samples of
2 the patient blood were sent to the central laboratory, which was Icon.

3 109. CW19 confirmed that MB Quest was a contract research organization
4 (“CRO”) overseeing the Phase II Trial at the investigator sites in Europe.

5 110. Confidential Witness No. 6 (“CW6”) was the clinical trial coordinator
6 for the Phase II Trial in issue at one of the investigator sites in California. As the
7 clinical trial coordinator for the Phase II Trial in issue at this investigator site, CW6
8 has personal knowledge regarding the Phase II Trial.

9 111. CW6 confirmed that his/her office was one of the clinical sites
10 participating in the Phase II Trial.

11 112. CW6 confirmed that pursuant to the Protocol for this Phase II Trial in
12 issue, on every weekly visit by the patients assigned to the Phase II Trial, vials of
13 blood were drawn from the patients. Some of the blood was retained by the
14 investigator site and tested. The results of the tests were noted on the Case Report
15 Forms and the Case Report Forms were sent to Peregrine on a periodic basis.

16 113. CW6 also confirmed that blood drawn from patients on each weekly
17 visit was also sent, pursuant to the study Protocol, to the central laboratory where it
18 was also subjected to further tests. CW6 stated that the results of these tests were
19 sent to Peregrine and to those persons in charge of supervising the Phase II Trial,
20 which in this instance were Defendants Shan and Garnick.

21 114. Confidential Witness No. 7 (“CW7”) was the coordinator of clinical
22 trials (which included the Phase II Trial in issue) at one of the investigator sites in
23 Florida. As the clinical trial coordinator for the Phase II Trial in issue at this
24 investigator site, CW7 has personal knowledge regarding the Phase II Trial.

25 115. CW7 confirmed that, pursuant to the study Protocol, blood drawn on
26 the weekly patient visits was sent to the central laboratory for tests to be run and
27 reported to Peregrine.

28

1 116. Confidential Witness No. 8 (“CW8”) was the Clinical Research
2 Manager for the Phase II Trial in issue at one of the investigator sites on the eastern
3 coast of the United States other than Florida. As the Clinical Research Manager for
4 the Phase II Trial at this investigator site, CW8 has personal knowledge regarding
5 the Phase II Trial.

6 117. CW8 confirmed that, pursuant to the study Protocol, blood was drawn
7 on every patient visit. The blood was tested at the investigator site and Case Report
8 Forms were completed and sent to Peregrine, with the results of the tests.

9 118. In addition, CW8 confirmed that other vials of patient blood drawn at
10 the time of each visit were sent, pursuant to the study Protocol, to the central
11 laboratory for further testing.

12 119. Confidential Witness No. 1 (“CW1”) is a former employee of Peregrine
13 and was employed in a high level managerial position in the capacity of Chief
14 Operating Officer (“COO”) from April 2009 through December 2011. CW1 was
15 responsible for all operations of the Company. CW1 stated that his/her job
16 responsibilities as COO included the obligation to manage and oversee Peregrine’s
17 subsidiary Avid Bioservices, Inc. (“Avid”) and all of Peregrine’s quality control
18 issues.

19 120. CW1 stated that the Company had a pattern and practice of announcing
20 positive preliminary data when, in his/her opinion, nothing should be announced
21 until the data was verified.

22 121. CW1 stated that the Company lacked internal controls related to
23 conducting clinical trials and reporting the data results of the clinical trials. CW1
24 further stated that there was a very secretive inner circle in the Company, which only
25 included Defendants King, Lytle, Shan and Garnick.

26 122. CW1 confirmed that patient blood is collected during clinical trials of
27 bavituximab and sent to the central laboratory for “safety lab” testing (meaning tests
28 to determine that the bavituximab was not making the patients sicker) and that the

1 results are regularly and periodically reported to Peregrine and specifically to
2 Defendant Shan.

3 123. CW1 confirmed that P-K testing was conducted at Peregrine by the
4 Process Sciences department, under the supervision of Director Connie Chang.
5 CW1 confirmed that Connie Chang reported directly to Defendant King. CW1 also
6 confirmed that the P-K testing was a test developed by Peregrine to detect the
7 presence of bavituximab in the patient's blood.

8 124. CW1 stated that Peregrine also performs HACA tests at their
9 headquarters.

10 125. Confidential Witness No. 2 ("CW2") is a former employee of
11 Peregrine's subsidiary Avid and was employed as Senior Vice President of
12 Manufacturing at Avid from October 1996 to July 2011. CW2 reported to CW1
13 during part of his/her employment with Avid.

14 126. CW2 stated that he/she was in charge of the manufacturing of all the
15 drugs which were used for the clinical tests at the Company, including the
16 bavituximab. The manufacturing included filling the vials for the bavituximab
17 clinical trials, which included the placebo and different strengths of the bavituximab
18 being tested. CW2 also stated that once the vials were filled they were shipped to a
19 third party vendor to have them labeled.

20 127. CW2 stated that Peregrine was trying to blame CSM for what he/she
21 believed to be Peregrine's mistakes.

22 128. CW2 stated that he/she was shocked at what Peregrine initially reported
23 regarding the data from the Phase II Trial. CW2 stated that the Company overstated
24 the positive nature of the data and the final positive data that the Company promised
25 was not present. CW2 further stated that the announced Phase II Trial results were
26 incredible and hard to believe.

27
28

1 129. Confidential Witness No. 3 (“CW3”) is a former employee of Peregrine
2 and was a Process Development Scientist at the Company from July 2010 to
3 September 2012.

4 130. CW3 stated that the P-K and HACA tests were conducted at Peregrine
5 using patient blood samples sent to Peregrine from the investigator sites and the
6 central lab.

7 131. CW3 stated that he/she reported directly to Connie Chang (Director of
8 the Process Sciences department at Peregrine). CW3 stated that Connie Chang was
9 in charge of conducting the P-K testing and the HACA antibody assay.

10 132. CW3 stated that the Company never performed its due diligence on any
11 project. CW3 stated that “[i]f the Company received good results on a project they
12 would never verify the results, they would just report the good news.”

13 133. CW3 further stated that the Company should have known that its Phase
14 II Trial could not be relied upon, as major discrepancies existed between patient
15 sample test results and patient treatment codes. CW3 stated that in “typical
16 Peregrine fashion a result that is beneficial to them is what they want. The Company
17 does not try to see if it is reproducible or even makes sense.” CW3 further stated
18 that “[i]n typical fashion they [Peregrine] looked at only the things that would make
19 their case look good and not what was actually occurring. Other people not even
20 intimately familiar with the Phase II Trial pointed out discrepancies in the safety
21 profile that should have caused them to take a second, third or fourth look.” CW3
22 stated, for example, that he/she observed internet posting from persons reviewing the
23 interim Phase II Trial results. Those postings commented that the placebo arm had
24 less desirable safety results than the 1 mg and 3 mg bavituximab arms. According to
25 CW3, this should have caused Peregrine to investigate why the placebo arm had a
26 worse safety record and should have enabled them to discover that placebo-
27 designated patients had received bavituximab in error.

28

1 134. CW3 also stated every decision ultimately is done by Steve King. “He
2 is not a scientist of any stature. I would say the intellectual honesty of a Peregrine
3 trial is very similar to those people who found WMDs in Iraq when none existed.
4 While I worked there I never heard one word from management about what is owed
5 the shareholders in terms of giving them a return, of being honest, of getting a drug
6 to market, of having any obligation to the shareholders. They got the result they
7 wanted to have, not the truth.”

8 135. CW3 confirmed that Defendants were successful, after touting the
9 interim and unverified results of the Phase II Trial, in inducing a potential partner,
10 Abbvie, Inc. (“Abbvie”), to review the data produced by the Phase II Trial. Abbvie
11 came on-site to Peregrine’s headquarters in late August 2012 to do an audit of the
12 results of the Phase II Trial. CW No. 3 believes, based on his experience at
13 Peregrine and the flurry of activity following the Abbvie on-site audit of Peregrine,
14 that it was Abbvie who discovered the “major discrepancies” in the data from the
15 results of the prior P-K testing performed at Peregrine. Abbvie then soured on a
16 partnership when Peregrine admitted that its prior statements about the results of the
17 data were false and misleading.

18 136. CW3 also confirmed that Defendant King flew to Chicago to meet with
19 representatives of Abbvie in an effort to keep them interested in a partnership with
20 Peregrine, but to no avail.

21 137. Upon information and belief, CW3 believes that Abbvie refused to do
22 business with a company or its executives who would be deliberately reckless in
23 releasing statements about the positive nature of clinical data before verifying the
24 accuracy of the data or the truth and accuracy of their own statements or who even
25 failed to verify which patients received which substance, placebo or bavituximab.

26 138. Abbvie is a major company in the industry of developing proprietary
27 drugs and bringing them to market. Abbvie is a spin-off from Abbott Laboratories,
28 Inc. (“Abbott”). On October 19, 2011, Abbott announced plans to separate into two

1 publicly traded companies, one in diversified medical products and the other in
2 research-based pharmaceuticals.

3 139. The diversified medical products company consisted of Abbott's
4 existing diversified medical products portfolio, including its branded generic
5 pharmaceutical, devices, diagnostic and nutritional businesses and retained the
6 Abbott name.

7 140. The research-based pharmaceutical company consisted of Abbott's
8 current portfolio of proprietary pharmaceuticals and biologics and was named
9 Abbvie.

10 141. At the time of the announcement, the Abbvie research-based
11 pharmaceutical division had delivered market-leading performance with a
12 sustainable mix of products and built a strong pipeline of proprietary medicines
13 through internal discovery, in-licensing and collaboration efforts.

14 142. At the time of the announcement, the Abbvie division had
15 approximately \$18 billion in annual revenue and had a sustainable portfolio of
16 market-leading brands, including Humira, Lupron, Synagis, Kaletra, Creon and
17 Synthroid. Abbvie also had an attractive pipeline of innovative R&D assets in
18 important specialty therapeutic areas such as Hepatitis C, immunology, chronic
19 kidney disease, women's health, oncology and neuroscience.

20 143. Abbvie continued as a division of Abbott until the actual separation
21 occurred on January 1, 2013.

22 144. Prior to the actual separation, Abbvie expressed an interest in a
23 collaboration partnership effort with Peregrine as to bavituximab after Peregrine
24 unblinded the Phase II Trial in May 2012 and began touting the interim data it was
25 releasing as positive and accurate.

26 145. A partnership with Abbvie would be everything that Peregrine and the
27 Individual Defendants had dreamed. Such a partnership would be a lifeline for
28 Peregrine and very lucrative for the Individual Defendants. To entice Abbvie into

1 partnership, during the Class Period, Defendants, with deliberate recklessness,
2 touted the efficacy of bavituximab and released public statements about the positive
3 (but unverified) results of the Phase II Trial in the hope no errors in the Phase II
4 Trial would be discovered.

5 146. Confidential Witness No. 4 (“CW4”) was a former consultant at
6 Peregrine for Clinical Operations from mid-2007 until March 2012.

7 147. CW4 stated that all the Peregrine clinical trials, including the
8 bavituximab clinical trial in issue, follow a standard set of operating procedures
9 (“SOPs”) and a Clinical Protocol specific to each clinical trial.

10 148. CW4 stated that the Clinical Protocol details all aspects of the clinical
11 trial including the drug supply, packaging, labeling, shipping arrangements, safety
12 procedures, patient population, preparation of Case Reports on patient treatment and
13 data gathered, manufacturing processes and all other steps in the clinical trial.

14 149. CW4 stated that the SOPs described how the data generated from the
15 clinical trial should be monitored to ensure its accuracy.

16 150. CW4 stated that all Peregrine employees involved in the trial are
17 required to follow the SOPs and the Clinical Protocol.

18 151. In addition, according to CW4, Peregrine has Case Report Forms that
19 are distributed to the clinical investigators and on which they are required to record
20 the data collected from the patients in the clinical trial. The data collected and
21 reported back to Peregrine by the clinical investigators includes the patient’s height,
22 weight, date of birth, sex, date of diagnosis, and reports of treatments, including the
23 results of diagnostic tests such as blood tests, radiology reports and
24 electrocardiograms.

25 152. CW4 stated that the SOPs, the Clinical Protocol and the Case Report
26 Forms for the Phase II Trial are found on the main frame computer at Peregrine’s
27 offices.
28

1 153. According to CW4, these documents are subject to non-disclosure
2 agreements signed by Peregrine employees which prevent them from releasing these
3 documents to outside parties without a subpoena.

4 154. According to CW4, the SOPs, Clinical Protocol and Case Report Forms
5 cannot be obtained from the FDA with a Freedom of Information Act (“FOIA”)
6 request as they are considered proprietary.

7 155. Plaintiff Fahey made a FOIA demand upon the FDA to obtain the
8 SOPs, the Clinical Protocol and the Case Report Forms on the Phase II Trial, but the
9 FDA refused to produce them.

10 156. Confidential Witness No. 5 (“CW5”) was a former project manager at
11 Clinical Supplies Management (“CSM”), the Contract Resource Organization
12 (“CRO”) hired by Peregrine to manage the bavituximab clinical trial in issue,
13 including the blinding of the drug and placebo vials and the distribution of the drug
14 and placebo vials to the clinical investigators.

15 157. CW5 stated that each clinical trial managed by CSM had its own set of
16 Standard Operating Procedures (SOPs) and had a Clinical Protocol supplied to CSM
17 by the drug company such as Peregrine conducting the clinical trial. These
18 documents were stored in the office of CSM in electronic format and hard copies
19 were maintained in large binders in the work area for easy reference by the CSM
20 workers.

21 158. CW5 stated that these documents were never supposed to leave the
22 CSM facility.

23 159. CW5 stated that he/she and other CSM employees signed
24 confidentiality agreements that would prevent them from revealing the contents of
25 the SOPs and Clinical Protocol without a lawful subpoena.

26 160. Confidential Witness No. 9 (“CW9”) was a former Peregrine Clinical
27 Research Associate who was employed at Peregrine from March 2011 through
28

1 January 2013. As a Clinical Research Associate, CW9 was personally familiar with
2 the Phase II Trial.

3 161. CW9 confirmed that blood is drawn from the patients at the clinical
4 investigation sites. CW9 also confirmed that local laboratories and the central lab
5 performed tests on the patient blood samples. The results of the blood tests were
6 entered into the Phase II Trial electronic database and sent to Peregrine.

7 162. CW9 also confirmed that all of the Case Report Forms are stored in the
8 Peregrine electronic database.

9 163. CW9 also stated that bavituximab targets part of the immune system
10 and suppresses particular proteins. CW9 stated that in the early stages of the
11 research into bavituximab, scientists looked at mice and saw what happens to
12 proteins in their body when they got the drug, and depending on what the mouse
13 blood results showed them, they developed a way to detect bavituximab.

14 164. CW9 confirmed that P-K testing detected whether bavituximab is in the
15 patient's blood and it also tells whether the drug is working and how long the drug
16 stays in the patient's body.

17 165. CW9 also confirmed that HACA can form in a human body dosed with
18 bavituximab because of the mouse DNA that is part of bavituximab.

19 166. CW9 confirmed that HACA tests were also performed at Peregrine.

20 167. CW9 also confirmed that Peregrine's subsidiary, Avid, can perform P-
21 K testing.

22 168. CW9 stated that she believed that P-K testing was performed sometime
23 after the study was unblinded in May of 2012, though he/she confirmed that P-K
24 testing could be done at any time on any patient's blood sample and if the P-K test
25 was performed after the study was unblinded, then the patient identification code
26 could be matched to the previously tested blood sample to determine whether it was
27 supposed to contain placebo or bavituximab.
28

1 169. CW9 confirmed that there is a Statistical Testing Timetable (also
2 sometimes called a Data Analysis Plan) which is in the Protocol that sets forth when
3 a particular event, such as P-K testing, should take place.

4 170. Confidential Witness No. 10 (“CW10”) is a former employee of
5 Peregrine and was employed as a Manager of Clinical Operations from March 2011
6 through July 2012. As Manager of Clinical Operations for Peregrine, CW10 has
7 personal knowledge regarding the Phase II Trial.

8 171. CW10 stated that Peregrine was disorganized and needed an Operations
9 Manager to push several clinical trials through to completion.

10 172. CW10’s job was to plan for several upcoming Phase III trials. This
11 included the drug Cotara, where all Phase II trials had been completed and the long
12 term survival rates had been received. In addition, there were Phase II trials
13 underway with bavituximab as an anti-cancer agent (which included the Phase II
14 Trial in issue). Finally, there was a Phase I trial near completion with an imaging
15 compound and Peregrine was planning for Phase II for the imaging compound.
16 CW10 had personal knowledge of the Phase II Trial in issue due to his/her
17 responsibility to oversee it.

18 173. CW10 described his job as Manager of Clinical Operations as a “high
19 level” view of how to strategize and move traffic through each clinical trial. In other
20 words, CW10 would strategize what companies to hire; what outside vendors to
21 hire; what the time flow would be on how the drugs would be manufactured and
22 shipped to outside contract research organizations and investigative sites; where
23 blood samples would be collected; when the patient blood samples would be tested
24 for “safety labs” and subjected to P-K testing and HACA testing; and by whom and
25 how reports would be generated. In other words, CW10 was responsible for creating
26 global flow charts for all clinical trials and overseeing the movement of drugs and
27 data from various CROs, investigator sites and the central lab to keep it all moving
28 and to get all clinical trials done in a timely and organized fashion.

1 174. CW10 also stated that there was a manager for each clinical study who
2 reported to him/her.

3 175. CW10 stated that there were tests to determine the presence of
4 bavituximab in the patient's blood stream: (i) a P-K test and (ii) a HACA test.

5 176. CW10 emphasized that there is a difference between P-K and HACA
6 testing.

7 177. CW10 confirmed that P-K testing detects the presence of bavituximab
8 in the patient's blood.

9 178. CW10 stated that another purpose of the P-K test is to test bavituximab
10 in the patient's blood and determine the rate of dosage of bavituximab and how the
11 half-life of bavituximab is affected as it is being processed by the human body.

12 179. CW10 confirmed that bavituximab is a drug that would generate HACA
13 (human anti-chimeric antibodies) because the body could recognize the mouse
14 portion of bavituximab as a foreign body and generate the anti-chimeric antibodies.

15 180. CW10 confirmed that Ms. Connie Chang was the Director of the
16 Process Sciences department at Peregrine.

17 181. CW10 stated that data generated by the P-K tests was sent to Ms.
18 Connie Chang and Defendant Shan in the form of a spreadsheet and it was linked to
19 a patient code using the ID assigned to each patient. A written narrative report was
20 then generated, analyzing the P-K test data on the spreadsheet. That written
21 narrative report then gets reviewed by Ms. Connie Chang and her department before
22 it is finalized and sent to Defendant Shan.

23 182. CW10 stated that the written report, when it is finalized, is in narrative
24 form and it discusses the technique and the process and gives an analysis of the
25 various data generated by the P-K testing. For example, "it would look at how the
26 concentration of bavituximab changed over time in the patient's blood, graphs would
27 be created from the data, and so on."
28

1 183. CW10 confirmed that a well-known P-K scientist whose name he/she
2 could not recall was retained by Peregrine to also review all of the data generated by
3 the P-K tests. This P-K scientist was an outside contractor who CW10 believed
4 worked with bavituximab previously. This P-K scientist would have produced a
5 report synthesizing all the P-K test results and sent it to Defendant Shan and Connie
6 Chang. CW10 confirmed that once the Phase II Trial was unblinded, Peregrine
7 conducted P-K tests to begin to analyze how bavituximab was working based on
8 which patient received which dosage.

9 184. CW10 believed based on his/her tenure with Peregrine that Peregrine
10 itself developed the P-K test to detect the presence of bavituximab because no other
11 entity would have had access to sufficient quantities of the drug to develop such a
12 test.

13 185. CW10 stated that the Protocol would set forth all of the events and
14 when they should happen. CW10 believes that all the patient blood samples were all
15 collected at the central lab. Thereafter, the blood samples were sent to Peregrine so
16 the Company could perform P-K, HACA and biomarker tests. A biomarker is a
17 measurable characteristic that reflects the severity or presence of some disease state.
18 More generally, a biomarker is anything that can be used as an indicator of a
19 particular disease state or some other physiological state of an organism.

20 186. CW10 stated that Icon, the central lab, probably did the “safety labs,”
21 meaning regular blood tests to determine that the bavituximab was not making the
22 patients sicker. As to the collection of blood samples, CW10 stated that some
23 investigator sites hold the blood for the entire trial and send it all at once and other
24 investigator sites send the blood each time it is collected in waves to either the
25 central lab or Peregrine.

26 187. CW10 confirmed that the results of the P-K testing would be
27 meaningful once the Phase II Trial results were unblinded and the patient codes were
28 applied to each P-K test so that Peregrine could determine whether that patient had

1 received bavituximab, what dosage that patient received, when was the blood drawn,
2 and how long was the bavituximab present in their blood.

3 188. Confidential Witness No. 21 (“CW21”) was an employee of Peregrine
4 from August 2007 to July of 2011. CW21’s job duties included business
5 development for Peregrine and Avid. CW21 split his time equally between
6 Peregrine and Avid.

7 189. CW21’s duties for Peregrine were to find commercial business partners
8 who would help Peregrine share the cost of developing bavituximab as a commercial
9 drug. CW21 stated that he was unsuccessful in ever finding any other entity,
10 including Abbvie and numerous other “big players,” willing to partner with
11 Peregrine to develop bavituximab as a commercial drug.

12 190. The work CW21 performed for Avid was to find customers who would
13 hire Avid to do manufacturing work.

14 191. CW21 confirmed that Peregrine developed an ELISA based assay
15 which could detect the presence of bavituximab in patient blood samples.

16 192. CW21 confirmed that a patient blood sample could be tested to
17 determine if bavituximab was present in the blood and that this could be done at any
18 time Peregrine had a patient blood sample to test.

19 193. Confidential Witness No. 11 (“CW11”) is a former employee of
20 Peregrine and was employed as a Research Associate with the Process Sciences
21 department for approximately three (3) years. CW11 left Peregrine in approximately
22 November of 2012. As a Research Associate with the Process Sciences department
23 for Peregrine, CW11 has personal knowledge regarding the Phase II Trial.

24 194. CW11 stated that the corporate culture of Peregrine was one of secrecy
25 and to keep lower level people in the dark and not to encourage questions. CW11
26 stated that Connie Chang is the Director of the Process Sciences department at
27 Peregrine. Then, there were two supervisors – Janet Doerr and Gary Larson.
28

1 CW11's supervisor was Gary Larson and then there were associates such as him/her
2 under the supervisors.

3 195. CW11 stated from his/her own personal knowledge, P-K testing was
4 performed at Peregrine.

5 196. CW11 stated that P-K testing was a standard type of test to measure the
6 content of something (bavituximab) in a sample. In this case, CW11 stated that the
7 patients' blood is received by Peregrine in a 1.5 milliliter test tube. The blood
8 comes from the clinic or the central laboratory in small boxes with 80 to 100 tubes
9 arranged in slots like little wine racks. CW11 also stated that the P-K testing
10 performed by Peregrine is designed to test for the presence of bavituximab in human
11 blood. It is simple to do and could be done at any time on any patient blood sample.

12 197. CW11 also stated that during the P-K test (which is an ELISA based
13 assay), the sample of the patient's blood is put on a plate and then usually another
14 antibody is applied to the blood to capture the thing of interest, in this case the
15 bavituximab. Then TMB, a second chemical, is added to the plate, which causes the
16 sample to change color. Then, according to CW11, the sample is run through a
17 spectrum analysis and based on the amount of the color change, a graph can be
18 generated and other data can be extrapolated to measure dose response, how much
19 bavituximab is in the patient's body, what is the concentration per liter of volume
20 and other things.

21 198. CW11 stated that Peregrine's P-K test to detect the presence of
22 bavituximab takes five (5) to six (6) hours to perform and is a normal standard test
23 that is frequently conducted and it is relatively inexpensive to perform. According
24 to CW11, "you can let the plate sit so the chemicals can react, and leave your office
25 to do other tests or work."

26 199. CW11 stated that as many as ten (10) different patient blood samples
27 can be applied to the plate on which the P-K test is performed and that a research
28

1 scientist such as himself could, and does, easily simultaneously monitor at least four
2 (4) plates with ten (10) different patient blood samples per plate.

3 200. CW11 stated that four (4) plates times ten (10) different patient blood
4 samples per plate equals forty (40) different patient samples. Thus, three (3)
5 research scientists could test the entirety of the 117 patient cohort in the Phase II
6 Trial for all three arms (placebo, 1 mg of bavituximab and 3 mg of bavituximab) in
7 five (5) to six (6) hours, or one Peregrine research scientist could test all patients'
8 blood samples in fifteen (15) to eighteen (18) hours.

9 201. CW11 stated that as early as May 21, 2012, when the study was
10 unblinded, Peregrine had the ability to conduct a P-K test in five (5) to eighteen (18)
11 hours to confirm the presence or absence of bavituximab in patient blood samples of
12 every single patient in this Phase II Trial depending on whether Peregrine wanted to
13 deploy one (1) scientist or three (3) to conduct the P-K tests.

14 202. CW11 stated that Mike Brown and Gary Larson were the persons who
15 performed the actual P-K testing for the Phase II Trial in issue.

16 **DEFENDANTS' MATERIALLY FALSE AND MISLEADING**
17 **STATEMENTS ISSUED DURING THE CLASS PERIOD**

18 203. A "Case Report Form" is defined by Section 1.10 of E6 of the ICH on
19 Good Clinical Practices as "a printed, optical, or electronic document designed to
20 record all of the protocol required information to be reported to the sponsor on each
21 trial subject."

22 204. On May 21, 2012, Peregrine unblinded the Phase II Trial. At that point
23 in time, Peregrine (as the sponsor) had, upon information and belief based on
24 interviews with confidential witnesses as to how the Phase II Trial was conducted,
25 all of the patient Case Report Forms listing the treatments received, tests conducted
26 and data gathered to date and Peregrine had in its possession and under its control all
27 patient blood samples.
28

205. As of May 21, 2012, Peregrine (as the sponsor) also had the ability to verify the accuracy of the unblinded clinical data gathered to date and confirm through P-K testing of patient blood samples that each patient in the Phase II Trial had received the proper dose assigned to them (placebo, 1 mg or 3 mg of bavituximab). *See, e.g.*, CW9 (¶ 168), CW10 (¶¶ 183, 187), CW11 (¶¶ 63, 201), CW15 (¶ 103).

206. On May 21, 2012, the Company issued a press release entitled *Peregrine Announces Positive Top-Line Data from Randomized, Double-Blind Bavituximab Phase II Trial in Second-Line Non-Small Cell Lung Cancer -- Bavituximab Plus Chemotherapy Demonstrates Doubling of Overall Response Rates Versus Chemotherapy Alone -- 50% Improvement in Progression-Free Survival and Overall Survival Trends Support Phase III Development*.

207. Nowhere in this May 21, 2012 press release did Defendants disclose that the data was preliminary data which Peregrine had not verified as accurate. The following bold and italicized statements were materially false and misleading:

Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM) today announced ***positive top-line results*** from its randomized, double-blind, placebo-controlled Phase IIb trial evaluating two dose levels of bavituximab plus docetaxel versus docetaxel plus placebo (control arm) in patients with second-line non-small cell lung cancer (NSCLC). ***Data from the trial showed a doubling of overall response rates (ORR), the primary endpoint, and an improvement in progression-free survival (PFS), a secondary endpoint, in patients treated in the bavituximab-containing arms when compared to the control arm. [...]***

Based on independent radiology reviews and current status of patients, top-line data from the trial are as follows:

Treatment Arm	Placebo plus docetaxel	Bavituximab (1 mg/kg) plus docetaxel	Bavituximab (3 mg/kg) plus docetaxel)
Overall Response Rate	7.9%	15%	17.9%
Median Progression-Free Survival	3.0 months	4.2 months	4.5 months

The compelling results from this rigorously designed trial clearly demonstrate that the combination of bavituximab and docetaxel is more active than docetaxel alone in treating second-line non-small cell lung cancer. We saw twice as many patients demonstrating an objective tumor response, increased progression-free survival, and already promising survival trends in this refractory setting. [...]

* * *

“After working on 17 drug approvals, it is data like this that continues to energize me. *These robust data* will be important in discussions with the FDA regarding advancing bavituximab’s clinical development in second-line non-small cell lung cancer,” said Robert Garnick, PhD, head of regulatory affairs at Peregrine. “We look forward to working closely with the FDA to identify the most efficient path toward commercialization for this

1 promising candidate in this indication where new
2 therapies are desperately needed.”

3 * * *

4 *“These data are a significant validation of the clinical*
5 *potential of bavituximab for patients with few effective*
6 *treatment options.* These data will be instrumental in
7 planning Phase III development in NSCLC and we are
8 excited to share these data as part of ongoing partnering
9 discussions,” said Steven W. King, president and chief
10 executive officer of Peregrine.

11 (Emphasis added).

12 208. Notably, in the May 21, 2012 press release, Defendants misleadingly
13 informed shareholders that Defendants themselves “saw” (*see, e.g., “we saw”*) the
14 claimed advantages of bavituximab, but gave no indication that Defendants had not
15 verified the accuracy of the data or confirmed through P-K testing of the patient
16 blood samples that the patients received the correct assigned dosage of placebo or
17 bavituximab.

18 209. On this news, Peregrine stock traded up from \$0.44 to \$0.53.

19 210. According to Defendants’ admissions in the September 24, 2012 press
20 release and later, all the unverified data reported regarding the placebo and 1 mg
21 arms in the Phase II Trial was false and misleading and any conclusions drawn
22 comparing the 3 mg arm results to the results of the placebo and 1 mg arms were
23 false and misleading. Defendants later admitted they did not know which patients
24 received the placebo or the 1 mg dosage when they were touting the data as true and
25 accurate.

26 211. On July 16, 2012, the Company issued a press release entitled
27 *Peregrine Pharmaceuticals Reports Fourth Quarter and Fiscal Year 2012 Financial*
28 *Results and Recent Developments -- Exceptional Data from Bavituximab Proof-of-*

1 *Concept Phase II Trial in Second-Line NSCLC Validates Platform and Positions*
 2 *Program for Phase III Development -- Wholly-owned Subsidiary Reports Record*
 3 *Revenue and Over \$30 Million in Revenue Backlog from Contract Manufacturing*
 4 *Business.* (Emphasis added).

5 212. Nowhere in the July 16, 2012 press release did Defendants disclose that
 6 the data was preliminary data which Peregrine had not verified as accurate nor did
 7 Defendants disclose that they failed to confirm through P-K testing of the patient
 8 blood samples which patients received which substance, placebo or bavituximab.
 9 The following bold and italicized statements below were materially false and
 10 misleading for the reasons discussed in ¶ 210 (above):

11 “Since our last quarterly update, we reported
 12 *transformational data* from a robust double-blinded,
 13 placebo-controlled Phase II proof-of-principle trial
 14 evaluating the potential of bavituximab in treating
 15 second-line non-small cell lung cancer patients. *The*
 16 *doubling of tumor response rates, a 50% increase in*
 17 *median progression free survival, and trends toward*
 18 *significant improvement in median overall survival*
 19 strongly support advancing the program toward Phase III
 20 development.” said Steven W. King, president and chief
 21 executive officer of Peregrine. “We could not be happier
 22 with the *strength of the data* from this robustly designed
 23 trial which gives us a clear direction and greatly enhances
 24 the probability of success as we look to Phase III
 25 development”

26 (Emphasis added).

27 213. On this news, Peregrine stock traded up from \$0.97 to \$1.06.
 28

214. The following bold and italicized statements in the Company's 2012 Form 10-K were materially false and misleading regarding the Phase II Trial for the reasons discussed in ¶ 210 (above):

In May 2012, we announced *positive top-line data* from this trial from 117 evaluable patients, based on independent radiology reviews and current status of patients as of that date, as shown in the following table:

Treatment Arm	Placebo plus docetaxel	Bavituximab (1 mg/kg) plus docetaxel	Bavituximab (3 mg/kg) plus docetaxel
<i>Overall Response Rate</i>	7.9%	15%	17.9%
<i>Median Progression-Free Survival</i>	3.0 months	4.2 months	4.5 months

Both dose levels of bavituximab and docetaxel combination treatment were generally safe and well tolerated with adverse events being similar to the patients receiving docetaxel with placebo. Another secondary endpoint, median OS, in the control arm has already been determined at less than 6 months, while the median has not been reached in either bavituximab-containing arm. We anticipate announcing median OS from this trial in the second half of calendar year 2012, but this is a time-to-event endpoint and could take longer to reach.

1 Based on these *encouraging data* and our discussions
2 with medical advisors, our strategy is to pursue Phase III
3 development with bavituximab in second-line NSCLC.
4 (Emphasis added).

5 215. On July 16, 2012, the Company conducted a Fourth Quarter 2012
6 Earnings Conference Call (“4Q Conference Call”). It was on this call that
7 Defendant King, President, CEO and a director of the Company, falsely stated:

8 It has been a transformational time at Peregrine since our
9 last quarterly conference call. Since that call, *our lead*
10 *clinical program, bavituximab, yielded exceptional*
11 *proof of principle data that was announced May 21,*
12 [2012] when the trial testing bavituximab in combination
13 with docetaxel versus docetaxel alone was unblinded.

14
15 *Results from the study showed a doubling of tumor*
16 *shrinkage or tumor response; 50% improvement in*
17 *progression-free survival, or PFS; and a significant*
18 *trend in overall survival, or OS, in which median OS*
19 *has already been reached in the docetaxel alone arm,*
20 *and a majority of patients are still alive in both*
21 *bavituximab-containing arms of the trial. [...].*

22
23 * * *

24 *The strength of this data* in this large area of high unmet
25 medical need has also sparked a surge in partnering
26 discussions that has included over 15 in-person
27 partnering meetings since that time with major players in
28

1 oncology, with follow-up discussions ongoing and
 2 additional parties showing interest.
 3 (Emphasis added).

4 216. The preceding bold and italicized statements made by Defendant King
 5 in the 4Q Conference Call were materially false and misleading regarding the Phase
 6 II Trial for the reasons discussed in ¶ 210 (above).

7 217. In addition, at no time during the 4Q Conference Call did Defendant
 8 King warn the market that Peregrine had not verified the accuracy of the data, had
 9 not confirmed through P-K testing of the patient blood samples that those patients
 10 assigned to receive placebo or 1 mg bavituximab had actually received the assigned
 11 dose, and thus none of the Defendants knew whether the statements they were
 12 making were true.

13 218. In that same 4Q Conference Call, Defendant Shan, Vice President of
 14 Clinical and Regulatory Affairs, falsely stated:

15 *We truly could not have expected anything more from*
 16 *this successful proof of concept trial, in which not only*
 17 *did the control arm produce expected results, but both*
 18 *bavituximab doses yielded similar improved efficacy*
 19 *results, as we expected going into the study, which*
 20 *mirrored the consistently positive trend across all*
 21 *efficacy end points that we observed in our prior single*
 22 *arm studies, as well as our overall clinical experience to*
 23 *date with bavituximab. We have also conducted further*
 24 *analyses of the top line results, and determined that not*
 25 *only were baseline characteristics well-balanced across*
 26 *all treatment groups, but there are no subgroup*
 27 *differences in geography, age, gender, race, et cetera.*
 28 And because of the rigorous trial design, these data have

1 ignited a great deal of excitement within the medical
2 community, with our clinical advisors as well as thought
3 leaders in the field supporting advancement to Phase III.
4 (Emphasis added).

5 219. The preceding bold and italicized statements made by Defendant Shan
6 in the 4Q Conference Call were materially false and misleading regarding the Phase
7 II Trial for the reasons discussed in ¶ 210 (above).

8 220. In addition, at no time during the 4Q Conference Call did Defendant
9 Shan warn the market that Peregrine had not verified the accuracy of the data, had
10 not confirmed that those patients assigned to receive placebo or 1 mg bavituximab
11 had actually received the assigned dose, and thus none of the Defendants knew
12 whether the statements they were making were true.

13 221. However, Defendant Shan's statement that Peregrine had "conducted
14 further analyses" of the results of the Phase II Trial misleadingly led investors to
15 believe that the Company had verified the accuracy of the data and thus was
16 truthfully reporting the results of the Phase II Trial.

17 222. On August 30, 2012, the Company announced that it had secured a \$30
18 million term loan from the Oxford Group Lenders. Under the loan facility, the
19 Company received initial funding of \$15 million and had the option to receive an
20 addition \$15 million.

21 223. On this news, Peregrine stock traded up from \$2.47 to \$2.51.

22 224. Defendants were able to secure the loan and draw down the first tranche
23 as a result of the false and misleading statements (¶¶ 47, 48) regarding the Phase II
24 Trial.

25 225. On September 7, 2012, the Company issued a press release announcing
26 data from the Phase II Trial was presented at the 2012 Chicago Multidisciplinary
27 Symposium in Thoracic Oncology. According to the Company, the results indicated
28 that lung cancer patients taking bavituximab lived twice as many months as those

1 treated with only chemotherapy. (*“The interim data showed a statistically*
2 *significant improvement in overall survival (Hazard Ratio 0.524, p-value .0154)*
3 *and a doubling of median overall survival (OS) in the bavituximab-containing*
4 *arms compared to the control arm.”*) (Emphasis added). This statement was false
5 and misleading. Defendants also claim that the patients given a lower dose of
6 bavituximab and the chemotherapy drug docetaxel lived for a median of 11.1
7 months compared with 5.6 months for patients treated with the chemotherapy drug
8 and a placebo. Patients given a higher dose of the drug lived for a median of 13.1
9 months, resulting in a pooled survival time of 12.1 months for the treated group.
10 These statements were false and misleading for the reasons discussed in ¶ 210.

11 226. The Company’s September 7, 2012 press release also falsely stated in
12 relevant part:

13 *“This study was a rigorous trial designed to minimize*
14 *bias and we are encouraged that this trial yielded such*
15 *positive results in the most important endpoint, overall*
16 *survival. The positive overall response rates and*
17 *progression free survival in both bavituximab-*
18 *containing arms seen earlier in the study has now*
19 *translated into a statistically significant extension in*
20 *overall survival for patients, a result rarely achieved in*
21 *phase II clinical trials.”* said Joseph Shan, vice president
22 of clinical and regulatory affairs at Peregrine. *“The*
23 *quality of this data gives us a solid foundation for*
24 *designing a Phase III trial with an increased probability*
25 *of success.* We are planning for an end-of-phase II
26 meeting with the FDA as we plan to initiate this trial by
27 mid-2013.”
28

1 The trial enrolled 121 patients (117 evaluable per the
2 study protocol) with second-line non-squamous NSCLC
3 following one prior chemotherapy regimen at over 40
4 clinical centers. Patients were equally randomized to 1
5 of the 3 treatment arms, docetaxel (75mg/m²) plus either
6 placebo, 1 mg/kg bavituximab, or 3 mg/kg bavituximab
7 until disease progression. Approximately 50% of the
8 patients were enrolled in the U.S. and 50% were enrolled
9 internationally with equal distribution between all
10 treatment groups.

11
12 *“Robust data from this Phase II trial clearly*
13 *demonstrate a significant benefit in overall survival*
14 *with a good safety profile in patients receiving*
15 *bavituximab plus docetaxel compared to those receiving*
16 *docetaxel plus placebo,”* said Steven W. King, president
17 and chief executive officer of Peregrine. [...]

18
19 *The interim results from the study showed no*
20 *significant safety differences between the three*
21 *treatment arms as determined by the trial’s independent*
22 *data monitoring committee.* Baseline characteristics
23 were well balanced across all three treatment arms of the
24 study, including performance (ECOG) status, age,
25 gender, and race. Tumor responses were determined in
26 accordance with Response Evaluation Criteria In Solid
27 Tumors (RECIST 1.1) based on blinded central radiology
28 review.

1
2 ***“The median overall survival results from the Proof-of***
3 ***Concept study are truly outstanding and great news for***
4 ***patients. [...]***

5 (Emphasis added).

6 227. The preceding bolded and italicized statements in the September 7,
7 2012 press release were false and misleading for the reasons discussed in ¶ 210. In
8 addition, the September 7, 2012 press release failed to warn the market that
9 Peregrine had not verified the accuracy of the data, had not confirmed through P-K
10 testing of the patient blood samples that those patients assigned to receive placebo or
11 1 mg bavituximab had actually received the assigned dose, and thus none of the
12 Defendants knew whether the statements they were making were true.

13 228. After this news, the Company’s stock rose from \$3.07 to close on
14 September 7, 2012 at \$4.50.

15 229. On September 10, 2012, the Company issued a press release
16 announcing its First Quarter fiscal year 2013 financial results.

17 230. The September 10, 2012 press release noted that the Phase II Trial was
18 unblinded in May 2012 (“We have achieved major milestones since the end of last
19 quarter with the ***unblinding of our proof-of-principle bavituximab study in second-***
20 ***line NSCLC in May*** and the recent announcement of overall survival data from the
21 study being the most significant.”) (Emphasis added).

22 231. Further, the September 10, 2012 press release falsely stated the
23 following:

24 [...] ***The statistically significant overall survival seen in***
25 ***that study is an obvious green light for us to begin plans***
26 ***to advance the program into phase III and goes a long***
27 ***way toward validating the technology platform,”*** said
28

1 Steven W. King, president and chief executive officer of
 2 Peregrine.
 3 (Emphasis added).

4 232. The preceding bolded and italicized statements in the September 10,
 5 2012 press release were false and misleading for the reasons discussed in ¶ 210. In
 6 addition, the September 10, 2012 press release failed to warn the market that
 7 Peregrine had not verified the accuracy of the data, had not confirmed through P-K
 8 testing of the patient blood samples that those patients assigned to receive placebo or
 9 1 mg bavituximab had actually received the assigned dose, and thus none of the
 10 Defendants knew whether the statements they were making were true.

11 233. On September 10, 2012, the Company conducted its First Quarter 2013
 12 Conference Call (“1Q Conference Call”). It was on that call that Defendant King
 13 stated the following:

14 Since the beginning of last quarter, it has been an
 15 exceptional time for Peregrine, as we have seen two of
 16 the most important milestones in the Company history
 17 achieved, transitioning the Company toward late-stage
 18 drug development. *The exclamation point for these*
 19 *milestones came just last Friday with the report that*
 20 *patients receiving Bavituximab plus chemotherapy in*
 21 *our proof-of-concept studying second-line non-small-*
 22 *cell lung cancer had double the median overall survival*
 23 *compared to patients receiving chemotherapy plus*
 24 *placebo. These are truly remarkable results that are not*
 25 *only great for the program, providing a clear signal to*
 26 *proceed toward a Phase III clinical trial, providing*
 27 *proof of concept that Bavituximab is an active drug*
 28

1 *when given with Docetaxel, but also great news for the*
 2 *non-small-cell lung cancer patients in the trial.*

3 (Emphasis added).

4 234. Defendant Kings' bolded statements in paragraph 233 (above) were
 5 materially false and misleading for the reasons set forth in ¶ 210 above.

6 235. In addition, Defendant King failed to warn the market that Peregrine
 7 had not verified the accuracy of the data, had not confirmed through P-K testing of
 8 the patient blood samples that those patients assigned to receive placebo or 1 mg
 9 bavituximab had actually received the assigned dose, and thus none of the
 10 Defendants knew whether the statements they were making were true.

11 236. At the same 1Q Conference Call, Defendant Shan stated in relevant
 12 part:

13 *Bavituximab continues to demonstrate a favorable*
 14 *safety profile, with a combination of Docetaxel plus*
 15 *Bavituximab being well tolerated, with no increase in*
 16 *frequency or nature of adverse events compared to the*
 17 *control arm.* Notably, no increase in bleeding or clotting
 18 adverse events were reported with the addition of
 19 Bavituximab, unlike the experience with other
 20 compounds which target blood vessels.

21
 22 In terms of efficacy outcomes, let me start with the
 23 primary endpoint, overall response rate, or ORR, which
 24 was determined by independent central radiology reviews
 25 according to RECIST criteria, or Response Evaluation
 26 Criteria in Solid Tumors. *As reported in May when the*
 27 *study was initially unblinded, the response rate in the*
 28 *Docetaxel plus placebo arm was 8% compared to 15%*

1 *in the Bavituximab 1-milligram per kilogram arm. And*
 2 *18% in the Bavituximab 3-milligramper kilogram arm.*
 3 *And 16.5% in the pooled Bavituximab arm.*

4 (Emphasis added).

5 237. Defendant Shan's bold and italicized statements in paragraph 236
 6 (above) were materially false and misleading for the reasons set forth in ¶ 210
 7 above.

8 238. In addition, Defendant Shan failed to warn the market that Peregrine
 9 had not verified the accuracy of the data, had not confirmed through P-K testing of
 10 the patient blood samples that those patients assigned to receive placebo or 1 mg
 11 bavituximab had actually received the assigned dose, and thus none of the
 12 Defendants knew whether the statements they were making were true.

13 239. At the same 1Q Conference Call, Defendant Garnick, Head of
 14 Regulatory Affairs at the Company, stated in relevant part:

15 As you have just heard from Joe, *the data we announced*
 16 *last week has far exceeded our expectations.* [...]

17 (Emphasis added).

18 240. Defendant Garnick' statements in paragraph 239 (above) were
 19 materially false and misleading for the reasons set forth in ¶ 210 above.

20 241. In addition, Defendant Garnick failed to warn the market that Peregrine
 21 had not verified the accuracy of the data, had not confirmed through P-K testing of
 22 the patient blood samples that those patients assigned to receive placebo or 1 mg
 23 bavituximab had actually received the assigned dose, and thus none of the
 24 Defendants knew whether the statements they were making were true.

25 242. At the same 1Q Conference Call, Defendant Lytle, CFO of the
 26 Company, stated in relevant part:

27 *This second tranche becomes available to us upon the*
 28 *attainment of certain pre-determined milestones, one of*

1 *which was just achieved last Friday with the*
 2 *announcement of the positive overall survival data from*
 3 *our second-line lung cancer trial. [...]*

4 (Emphasis added).

5 243. Defendant Lytle's statements in paragraph 242 (above) were materially
 6 false and misleading for the reasons set forth in ¶ 210 above.

7 244. In addition, Defendant Lytle failed to warn the market that Peregrine
 8 had not verified the accuracy of the data, had not confirmed through P-K testing of
 9 the patient blood samples that those patients assigned to receive placebo or 1 mg
 10 bavituximab had actually received the assigned dose, and thus none of the
 11 Defendants knew whether the statements they were making were true.

12 245. On September 10, 2012, the Company filed its 1Q 2013 Form 10-Q.
 13 The 1Q 2013 Form 10-Q contained the positive findings concerning bavituximab
 14 that were contained in the Company's September 7, 2012 press release. Defendants
 15 King and Lytle signed the 1Q 2013 Form 10-Q attesting to the accuracy of the
 16 information presented in the SEC filing.

17 246. The 1Q 2013 Form 10-Q stated the following regarding the Company's
 18 Phase II Trial in Second-Line Non-Small Cell Lung Cancer, and the statements in
 19 bold were materially false and misleading:

20 [...]
 21 *In May 2012, we announced positive top-line*
 22 *overall response rate ("ORR") data (primary endpoint)*
 23 *and median progression-free survival ("PFS") (one*
 24 *secondary endpoint) from this trial from 117 evaluable*
 25 *patients, based on independent radiology reviews and*
 26 *current status of patients as of that date, as shown in*
 27 *the following table:*
 28

Treatment Arm	Placebo plus docetaxel	Bavituximab (1 mg/kg) plus docetaxel	Bavituximab (3 mg/kg) plus docetaxel
<i>Overall Response Rate</i>	<i>7.9%</i>	<i>15%</i>	<i>17.9%</i>
<i>Median Progression-Free Survival</i>	<i>3.0 months</i>	<i>4.2 months</i>	<i>4.5 months</i>

In addition, on September 7, 2012, we presented compelling interim median overall survival data (“OS”), another secondary endpoint from the trial, at the 2012 Chicago Multidisciplinary Symposium in Thoracic Oncology. *The data presented showed a doubling of median OS in each of the bavituximab-containing arms compared to the control arm, representing a significant improvement in survival.*

(Emphasis added).

247. The 1Q 2013 Form 10-Q statements in bold were materially false and misleading for the reasons set forth in ¶ 210 above.

248. In addition, the 1Q 2013 Form 10-Q failed to warn the market that Peregrine had not verified the accuracy of the data, had not confirmed through P-K testing of the patient blood samples that those patients assigned to receive placebo or 1 mg bavituximab had actually received the assigned dose, and thus none of the Defendants knew whether the statements they were making were true.

249. Further, the statements made in ¶¶ 206, 207, 211, 212, 214, 215, 218, 225, 226, 230, 231, 233, 236, 239, 242, 246 (above) regarding the efficacy of bavituximab in treating second-line NSCLC patients were materially false and misleading because:

1 (a) Defendants had not properly administered and monitored the
2 Phase II Trial in accordance with Sections 5.1.1 of the ICH on Good Clinical
3 Practice, E6 (“***The sponsor is responsible for implementing and maintaining***
4 ***quality assurance and quality control systems*** with written SOPs to ensure
5 that trials are conducted and data are generated, documented (recorded), and
6 reported in compliance with the protocol, GCP, and the applicable regulatory
7 requirement(s)”) (Emphasis added). “Quality Assurance (QA)” is defined by
8 Section 1.46 of E6 of the ICH on Good Clinical Practices as “all those
9 planned and systematic actions that are established to ensure that the trial is
10 performed and the data generated, documented (recorded), and reported in
11 compliance with Good Clinical Practice (GCP) and the applicable regulatory
12 requirements.”;

13 (b) Defendants had not properly administered and monitored the
14 Phase II Trial in accordance with Section 5.1.3 of the ICH on Good Clinical
15 Practice, E6 (“Quality control should be applied to each stage of data handling
16 to ensure that all data are reliable and have been processed correctly”);

17 (c) Defendants had not properly administered and monitored the
18 Phase II Trial in accordance with Section 5.2.1 of the ICH on Good Clinical
19 Practice, E6 (“A sponsor may transfer any or all of the sponsor’s trial-related
20 duties and functions to a [Contract Research Organization] CRO, ***but the***
21 ***ultimate responsibility for the quality and integrity of the trial data always***
22 ***resides with the sponsor***”) (Emphasis added);

23 (d) Defendants had not properly administered and monitored the
24 Phase II Trial in accordance with Section 5.5.1 of the ICH on Good Clinical
25 Practice, E6 (“The sponsor should utilize appropriately qualified individuals
26 to supervise the overall conduct of the trial, to handle the data, to verify the
27 data, to conduct the statistical analyses, and to prepare the trial reports.”);
28

1 (e) Defendants had not properly administered and monitored the
2 Phase II Trial in accordance with Section 5.13.1 of the ICH on Good Clinical
3 Practice, E6 (“The sponsor should ensure that the investigational product(s)
4 (including active comparator(s) and placebo, if applicable) is characterized as
5 appropriate to the stage of development of the product(s), is manufactured in
6 accordance with any applicable GMP, and is coded and labeled in a manner
7 that protects the blinding, if applicable. In addition, the labeling should
8 comply with applicable regulatory requirement(s).”);

9 (f) Defendants had not properly administered and monitored the
10 Phase II Trial in accordance with Section 5.18.1 of the ICH on Good Clinical
11 Practice, E6 (“The purposes of trial monitoring are to verify that: . . . ***The***
12 ***reported trial data are accurate, complete, and verifiable from source***
13 ***documents.*** [...]”) (Emphasis added). “Source Documents” is defined by
14 Section 1.52 of E6 of the ICH on Good Clinical Practices as “original
15 documents, data, and records (e.g., hospital records, clinical and office charts,
16 laboratory notes, memoranda, subjects’ diaries or evaluation checklists,
17 pharmacy dispensing records, recorded data from automated instruments,
18 copies or transcriptions certified after verification as being accurate copies,
19 microfiches, photographic negatives, microfilm or magnetic media, x-rays,
20 subject files, and records kept at the pharmacy, at the laboratories and at
21 medico-technical departments involved in the clinical trial.”;

22 (g) Defendants had not properly administered and monitored the
23 Phase II Trial in accordance with Section 5.18.3 of the ICH on Good Clinical
24 Practice, E6 (“***The sponsor should ensure that the trials are adequately***
25 ***monitored.*** [...]”) (Emphasis added);

26 (h) Defendants had not properly administered and monitored the
27 Phase II Trial in accordance with Section 5.18.4(d) of the ICH on Good
28

1 Clinical Practice, E6 (“Verifying that the investigator follows the approved
2 protocol and all approved amendment(s), if any.”);

3 (i) Defendants had not properly administered and monitored the
4 Phase II Trial in accordance with Section 5.18.4(h) of the ICH on Good
5 Clinical Practice, E6 (“**Verifying** that the investigator and the investigator’s
6 trial staff are performing the *specified trial functions*, in accordance with the
7 protocol and any other written agreement between the sponsor and the
8 investigator/institution, and have not delegated these functions to
9 unauthorized individuals.”) (Emphasis added);

10 (j) Defendants had not properly administered and monitored the
11 Phase II Trial in accordance with Section 5.18.3 of the ICH on Good Clinical
12 Practice, E6 (“**The sponsor should ensure that the trials are adequately**
13 **monitored.** [...]”) (Emphasis added);

14 (k) Defendants violated FDA Guideline on the Preparation of
15 Investigational New Drug Products, 21 CFR § 211.125 (“**Strict control shall**
16 **be exercised over labeling issued for use in drug product labeling operations**
17 **. . . .**”) (Emphasis added);

18 (l) Defendants violated FDA Guideline on the Preparation of
19 Investigational New Drug Products, 21 CFR § 211.130 (“written procedures
20 be designed **and followed** to assure that correct labels and labeling materials
21 are used for drug products”) (Emphasis added);

22 (m) Defendants admitted in the Company’s 2012 Form 10-K that the
23 Company’s reliance on third parties does not relieve them of Good Clinical
24 Practice for conducting, monitoring, recording and reporting the results of
25 clinical trials to ensure that the data and results are scientifically credible,
26 accurate and viable; however, this statement was false as Defendants never
27 conducted a **thorough operational review** of the third-party vendor operation
28

1 to ensure the accuracy of their interim reporting of the Phase II Trial (as
2 Defendants later admitted to in the Company's January 7, 2013 press release);

3 (n) Defendants failed to properly ensure that "all clinical trial
4 information" was "recorded, handled and stored in a way that allows its
5 accurate reporting, interpretation and verification" in violation of Section
6 2.10 of the ICH on Good Clinical Practice, E6; and

7 (o) Defendants had not properly administered and monitored the
8 Phase II Trial in accordance with Section 5.18.4(k) of the ICH on Good
9 Clinical Practices, E6 ("**Verifying** that source documents and other trial
10 records are accurate, complete, kept up-to-date and maintained.") (Emphasis
11 added).

12 250. Furthermore, Peregrine lacked the proper internal controls related to
13 conducting clinical trials and reporting the results of the clinical trials (*see* CW1 (¶
14 121), CW3 (¶¶ 132, 133), CW10 (¶ 171)).

15 251. During the Class Period, the Company's reports on the significance of
16 the data from the Phase II Trial gave investors a false-positive conclusion of the
17 outcome from the Phase II Trial. Until a clinical study is completed and proper
18 administration of the study's medications to the patients is confirmed and analyzed,
19 a projected outcome based on partial data cannot be cited as statistical evidence of
20 safety or efficacy.

21 252. Further, one of the most important values that can be assigned to
22 findings by the process of statistical analysis is the p-value, or "probability" value.

23 253. The p-value is a number between 0.00 and 1.0, and is used to
24 demonstrate the strength of a conclusion drawn from clinical trial data. It enables
25 analysts to assign a widely accepted numerical value to the strength of a statement or
26 hypothesis. Essentially, the p-value measures consistency between the results
27 actually obtained in the trial and the "pure chance" explanation for those results.
28

1 254. A statement and corresponding p-value are considered of strong
2 significance if the probability of the same reaction occurring randomly or by chance
3 is less than one in twenty, or 5%, corresponding to a p-value of $p < 0.05$.

4 255. The Company made an announcement on September 7, 2012, about the
5 interim data as to the overall survival of patients purportedly gathered from the
6 Phase II Trial and claimed that the p-value was .0154. This p-value, if accurate,
7 would be statistically significant in showing that bavituximab had been efficacious
8 in the Phase II Trial. However, this description of the p-value as to the overall
9 survival of patients was false and misleading as it was based on false data. Peregrine
10 later admitted on February 19, 2013, that the p-value as to the overall survival of
11 patients was 0.217, which means that chance would be responsible for the outcome
12 of the data in more than one of five times, which is not statistically significant.
13 Peregrine also failed to disclose any reason for the extreme negative change as to the
14 p-value in the overall survival of patients from the earlier reported data.

15 256. On September 24, 2012, the Company issued a press release entitled
16 *Peregrine Pharmaceuticals Announces That It Has Discovered Major Discrepancies*
17 *in Treatment Group Coding by an Independent Third-Party Vendor Responsible for*
18 *Distribution of Blinded Investigational Product Used in Its Bavituximab Phase II*
19 *Second-Line Non-Small Cell Lung Cancer Trial*, which stated in relevant part:

20 Peregrine Pharmaceuticals announced today that during
21 the course of preparing for an end-of-phase II meeting
22 with regulatory authorities and following recent data
23 announcements from its randomized, double-blind
24 placebo-controlled Phase II trial of bavituximab in
25 second-line non-small cell lung cancer, ***it discovered***
26 ***major discrepancies between some patient sample test***
27 ***results and patient treatment code assignments***. Due to
28 the double-blind nature of the trial, Peregrine was not

1 permitted to have access to either patient group
2 assignments or related product coding information. As
3 part of the trial's execution, Peregrine contracted with
4 independent third-party contractors to execute treatment
5 group assignments and oversee clinical trial material
6 coding and distribution according to established
7 procedures. A subsequent review of information has
8 determined that the source of these discrepancies appear
9 to have been associated with the independent third-party
10 contracted to code and distribute investigational drug
11 product.

12
13 This discrepancy is specific to this trial and will have no
14 impact on other ongoing bavituximab trials.

15
16 Peregrine intends to communicate further as soon as it is
17 able to determine the impact of this issue. *In the*
18 *meantime, investors should not rely on clinical data that*
19 *the company disclosed on or before September 7, 2012*
20 *from its Phase II bavituximab trial in patients with*
21 *second-line non-small cell lung cancer or any*
22 *presentations or other documents related to this Phase*
23 *II trial.*

24 (Emphasis added).

25 257. After this news, the Company's stock plummeted \$4.23 per share to
26 close at \$1.16 per share on September 24, 2012, a one-day decline of 78%.

27 258. Further, the Company's September 24, 2012 press release directs
28 investors not to "rely on the clinical data that the company disclosed on or before

1 September 7, 2012” but it makes *no mention of the clinical data the company*
 2 *disclosed on September 10, 2012* (see ¶¶ 229-46 above). Defendants’ exclusion of
 3 the September 10, 2012 statements to investors in the September 24, 2012 press
 4 release was false and misleading as it gave the impression that the various
 5 statements made by Defendants on September 10, 2012 discussing the data from the
 6 Phase II Trial were still true and accurate when they were not.

7 259. On September 26, 2012, the Company filed a Form 8-K with the SEC,
 8 which disclosed that it had received a written notice of default from the Oxford
 9 Group Lenders on September 24, 2012 (*the same day* the Company issued a press
 10 release that investors should not rely on the clinical data), with respect to a security
 11 agreement the Company had entered into on August 30, 2012. According to the
 12 Company, the Oxford Group Lenders deemed the Company’s disclosure on
 13 September 24, 2012, concerning the major discrepancies in the results from its
 14 cancer trial to be a material adverse change under the terms of the loan agreement
 15 and, as result, the Oxford Group Lenders accelerated the repayment of the loan and
 16 demanded repayment in full for the outstanding amounts. The Company’s Form 8-
 17 K stated in relevant part:

18 On September 24, 2012, we received a written notice of
 19 default (“Notice of Default”) from Oxford Finance LLC,
 20 as collateral agent (“Collateral Agent”), on behalf of
 21 itself, Silicon Valley Bank, and MidCap Financial SBIC,
 22 LP (collectively, the “Lenders”), with respect to that
 23 certain loan and security agreement dated as of August
 24 30, 2012, by and among Peregrine, its wholly owned
 25 subsidiary, Avid Bioservices, Inc., and the Lenders (the
 26 “Loan Agreement”). *Pursuant to the Notice of Default,*
 27 *all amounts due under the Loan Agreement were*
 28 *accelerated as a result of the above event, which was*

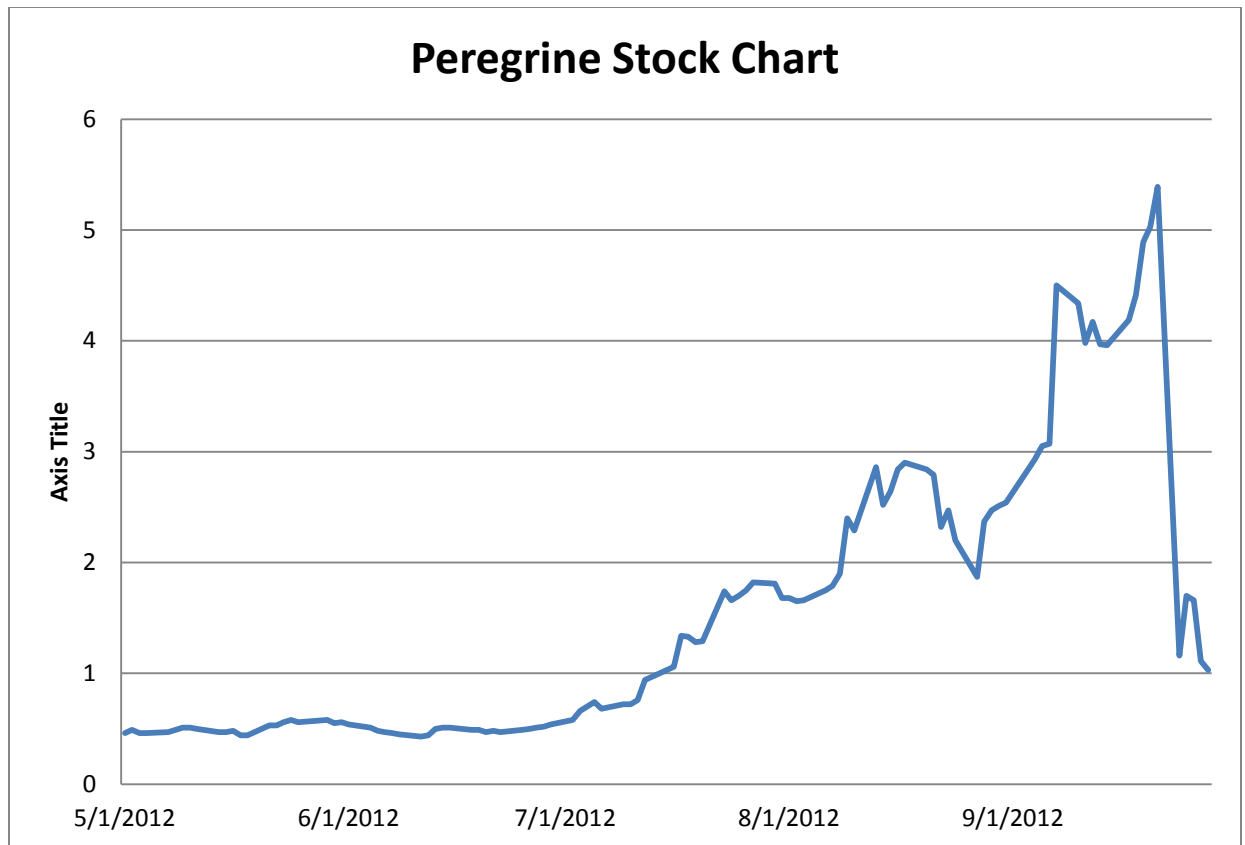
1 *deemed a material adverse change under the Loan*
2 *Agreement, and the Lenders demanded full payment of*
3 *all obligations under the Loan Agreement, including*
4 *the outstanding principal amount of \$15 million and all*
5 *accrued interest thereon, plus a final payment fee equal*
6 *to 6.5% of the principal amount repaid.* On September
7 25, 2012 Peregrine paid the Lenders all outstanding
8 obligations and the Loan Agreement was terminated.

9 (Emphasis added).

10 260. It is no coincidence that on September 24, 2012 all of the following
11 happened: (a) Peregrine announced the “major discrepancies” with the Phase II Trial
12 data; (b) Peregrine filed suit against CSM; and (c) Oxford Group Lenders called the
13 loan. The reasonable inference is that Peregrine had knowledge of the “major
14 discrepancies” many days in advance of September 24, 2012 in order to retain
15 counsel and research, prepare and file a complaint against CSM.

16 261. It is also a reasonable inference that Peregrine gave the Oxford Group
17 Lenders advanced information on the “major discrepancies” well in advance of
18 September 24, 2012 so that Oxford could consider its rights under the loan
19 documents and Peregrine could have an opportunity to attempt to persuade Oxford
20 not to call the loans.

21 262. On this September 26, 2012 news that Oxford Group Lenders was
22 calling its loan, the Company’s stock declined \$0.55 per share to close at \$1.11 per
23 share on September 27, 2012, a one-day decline of 33% as demonstrated in the chart
24 below:



263. Defendants' concealment that the Oxford Group Lenders had called the loan on September 24, 2012 was a material omission that further damaged investors.

264. As a result of Defendants' materially false and misleading statements made regarding the data gathered from the Phase II Trial from May 2012 through September 26, 2012, Peregrine securities traded at artificially inflated levels during the Class Period. However, after the September 24 and 26 statements by Defendants reached the market, the Company's shares were hammered by massive sales, sending them down first 78% and the 33%.

POST CLASS PERIOD ADMISSIONS

265. Defendants admit that it was through a "***routine collection*** of data in advance of the [C]ompany's end-of-Phase II meeting with regulatory authorities" that they discovered the discrepancies they claim existed in the randomized, double-blind placebo-controlled Phase II Trial of bavituximab in second-line NSCLC. See December 10, 2012 Company press release entitled *Peregrine Pharmaceuticals*

1 *Reports Second Quarter Fiscal Year 2013 Financial Results and Recent*
 2 *Developments* (emphasis added) and October 17, 2012 press release entitled
 3 *Peregrine Pharmaceuticals Provides Update on Corporate Activities* (“Peregrine is
 4 also conducting a detailed internal review into the discrepancies tied to the
 5 randomized, double-blind placebo-controlled Phase II trial of bavituximab in
 6 second-line NSCLC *that were discovered as part of the routine collection of data* in
 7 advance of the company’s end-of-Phase II meeting with regulatory authorities.”)
 8 (Emphasis added).

9 **A. The Individual Defendants Had Substantial**
 10 **Motivation to Make False and/or Misleading Statements**

11 266. Oxford is a lending institution with a long history of providing capital
 12 exclusively to life sciences and healthcare services companies throughout the world.
 13 Oxford prides itself on having a valued reputation for fairness and flexibility and
 14 claims to have achieved success by building solid relationships with its many clients.
 15 Oxford claims to have an extraordinarily knowledgeable lending team well-versed in
 16 science and healthcare and states that it works diligently to understand the specific
 17 goals of individual clients and provide sound financial solutions for their growth and
 18 development. Oxford prides itself on partnering with its clients for the long-term
 19 and represents that it is committed to serve as a steadfast resource to its clients.

20 267. MidCap is a commercial finance firm that focuses exclusively on
 21 providing debt solutions to middle-market life-science and healthcare companies.
 22 MidCap provides a broad array of products intended to finance the growth and
 23 manage the working capital of companies spanning the breadth of the healthcare
 24 industry. MidCap believes that companies in the life-science and healthcare
 25 industries need a lender that understands their business and has the creativity and
 26 flexibility to provide financing solutions that are suited to their needs. MidCap
 27 prides itself on its years of experience and strong balance sheet which make it the
 28 lender of choice for these companies.

1 268. SVB has \$23 billion in assets and more than 1,600 employees. SVB
2 provides commercial, international and private banking through 34 locations
3 worldwide. SVB prides itself on being the bank of choice for the world's most
4 innovative companies and exclusive wineries, and believes that its diverse financial
5 services, knowledge, global network, and world class service increase their clients'
6 probability of success. SVB also takes pride in being ranked by *Forbes* magazine as
7 America's Best Banks.

8 269. The Individual Defendants were deliberately reckless in their positive
9 touting of the unverified data of the Phase II Trial because they needed to achieve
10 positive results in this Phase II Trial in order to induce the Oxford Group Lenders to
11 make the loan and allow Peregrine to draw down the first tranche (\$15 million) of
12 money that could be borrowed.

13 270. Defendant Lytle admitted that Defendants' statements that the Phase II
14 Trial data was positive is what allowed Peregrine to satisfy one of the two (2)
15 conditions necessary before Peregrine could then draw down the second tranche of
16 \$15 million of the Oxford Group Lenders' loan facility. *See* ¶ 242.

17 271. It was therefore shocking that the Oxford Group Lenders would declare
18 a material adverse change in circumstances and accelerate the loan to Peregrine ***on***
19 ***the very day*** (September 24, 2012) that Peregrine announced to the market that its
20 prior statements about the interim data could no longer be relied upon.

21 272. The compelling inference is that the deliberate recklessness of
22 Peregrine and its management team (the Individual Defendants herein), in touting
23 the Phase II Trial data findings as positive to induce the Oxford Group Lenders to
24 make the loan without verifying the accuracy of the data and even failing to take the
25 rudimentary step of verifying that the patients who were supposed to receive the
26 placebo actually received it and those who were supposed to receive the 1 mg of
27 bavituximab actually received it, so alarmed the Oxford Group Lenders that it called
28 the loan.

1 273. Further, the Oxford Group Lenders had more to gain from the success
2 of the Phase II Trial than from calling the loan as they were issued warrants to
3 purchase stock as part of the loan agreement. Thus, the Oxford Group Lenders
4 would have profited more had Peregrine drawn down the full \$30 million as greater
5 interest would have accumulated, the stock would not have been further diluted, and
6 had the Phase III trial been successful, their warrants would be more valuable. At
7 that point, the warrants would have produced a large profit for the Oxford Group
8 Lenders. Only the deliberate recklessness of Defendants alarmed the Oxford Group
9 Lenders into terminating the lending relationship because of the “major
10 discrepancies” with the Phase II Trial data.

11 274. Moreover, the Oxford Group loan was critical to Peregrine as it: (i)
12 strengthened the Company’s balance sheet (*see* August 30, 2012 Company press
13 release entitled *Peregrine Pharmaceuticals Secures \$30 Million Loan Facility*
14 (“This loan facility strengthens our balance sheet . . .”)); (ii) provided the Company
15 with sufficient capital to fund its operations for 12 months as the Company advanced
16 toward Phase III development (*see id.* (“With the potential \$30 million in total
17 funding, we will have sufficient capital to fund our operations for at least the next 12
18 months . . .”)); (iii) demonstrated to the market that outside entities were confident in
19 the Phase II Trial; and (iv) stopped the issuance of Peregrine stock “at-the-market”
20 offerings (and in turn stopped the dilution of Peregrine stock harmful to the
21 Individual Defendants’ ownership interest).

22
23
24
25 ///

26 ///

27 ///

28

275. Defendants King, Lytle and Shan were also motivated to make false and misleading statements regarding the Phase II Trial in order to retain their positions and lucrative annual salaries. For example, Defendants received the following annual base salaries in 2012:

Defendant	Position	Annual Base Salary
King	CEO, President and Director	\$429,000
Lytle	CFO	\$325,812
Shan	VP, Clinical and Regulatory Affairs	\$260,000

276. Further, according to the Company's Form 10-K for fiscal year ended April 30, 2013 ("2013 Form 10-K"),¹ "[t]he approved target bonus percentages for named executive officers for fiscal year 2013, and each year thereafter unless and until modified by resolution of the Compensation Committee, were as follows: Steven W. King – 60%; Paul J. Lytle – 40%; [...] [and] Joseph S. Shan – 35%" "In addition, under the Bonus Plan, each participant's target bonus percentages can be further adjusted by a corporate factor ranging from 0 to 1.5 times, based on the Company's achievement of other factors as determined by the Compensation Committee, including but not limited to, performance of day-to-day responsibilities and participation in the achievement of the corporate goals and achievement of individual goals determined by the Compensation Committee."

277. In addition, according to the Company's 2013 Form 10-K, (*which covers the Company's fiscal quarters ending July 31, 2012 and October 31, 2012 – the First and Second Quarter of the Company's fiscal year*) "on July 8, 2013, following a detailed review of the status of the Company's fiscal year 2013 corporate goals, and each named executive officer's contribution to the attainment of such corporate goals, as well as his or her attainment of individual goals for fiscal

¹ Peregrine operates on a fiscal year calendar which ends April 30th of each year.

1 year 2013 (which includes *the Company's fiscal quarters ending July 31, 2012 and*
2 *October 31, 2012 – the First Quarter and Second Quarter of the Company's fiscal*
3 *year*), and such other factors under the Bonus Plan as the Compensation Committee
4 deemed relevant, the Compensation Committee approved and awarded the following
5 cash bonuses for fiscal year 2013 to the named executive officers pursuant to the
6 Bonus Plan: Steven W. King – \$313,706; Paul J. Lytle – \$158,833; [...] [and]
7 Joseph S. Shan – \$88,725. . . .”

8 278. Defendant Garnick is employed as a consultant to the Company in the
9 position as Head of Regulatory Affairs through Lone Mountain Biotechnology and
10 Medical Devices, Inc. Defendant Garnick was motivated to make false and
11 misleading statements regarding the Phase II Trial in order to retain his position as a
12 consultant to the Company.

13 279. On May 4, 2012, the Compensation Committee granted King an award
14 of 500,000 stock options under the Company's shareholder-approved 2011 Stock
15 Incentive Plan (the “Incentive Plan”). At the time the award was made, the
16 Incentive Plan limited the number of shares covered by an award that could be
17 granted to an executive officer in a fiscal year to 250,000. Specifically, Section 5.4
18 of the Incentive Plan stated: “the maximum number of shares of Stock that may be
19 granted to any one Participant, who is a Covered Employee, during any of the
20 Company's fiscal years with respect to one or more Awards shall be two hundred
21 fifty thousand (250,000).”

22 280. Further, even though the Company had recently disclosed on September
23 24, 2012 that the data announced from its Phase II Trial was not to be relied upon,
24 nonetheless, on December 27, 2012, Peregrine's Compensation Committee
25 “approved a broad base grant of stock options (“December 2012 Grants”) to
26 substantially all of the Company's employees, the Company's three non-employee
27 directors and four consultants to purchase an aggregate of 3,560,125 shares of
28 common stock.” Defendants King and Lytle each received 200,000 options and

1 Defendant Shan received 150,000 options. The Company further stated in its Form
2 8-K filed with the SEC on December 28, 2012 that the grants of options were “non-
3 routine” and that the Compensation Committee had deemed them necessary for the
4 following purposes:

5 promoting employee retention and in the best interest of
6 the Company and its stockholders given the Company’s
7 (i) recent agreement with the U.S. Food and Drug
8 Administration on the design of a single registration trial
9 for Cotara in patients with recurrent glioblastoma
10 multiforme and the need to focus significant time and
11 effort on moving this trial forward, including efforts to
12 seek a partner, (ii) *need to complete the Company’s*
13 *detailed internal review of its Phase II second-line non-*
14 *small cell lung cancer trial with bavituximab*, (iii) need
15 for its biomanufacturing subsidiary, Avid Bioservices, to
16 meet its existing customer obligations, plus continue to
17 expand its client base, and (iv) need to meet other
18 corporate goals and objectives, all of which are necessary
19 to continue to maintain and enhance stockholder value.

20 (Emphasis added).

21 281. In other words, the Individual Defendants were being rewarded for
22 verifying now the Phase II Trial data they should have verified previously through
23 simple P-K testing before they falsely touted its accuracy and importance.

24 282. That same day, the Company’s Compensation Committee approved
25 increases in annual base salary for Peregrine’s Executive Officers. The
26 Compensation Committee raised Defendant King’s salary to \$446,160, Defendant
27 Lytle’s salary to \$338,844, and Defendant Shan’s to \$270,400.

283. In addition, as demonstrated in ¶¶ 27, 28, 29 above, Defendants King, Shan and Lytle all succeeded in increasing their stock ownership in the Company from fiscal year end 2012 to fiscal year end 2013.

284. Defendants' motive to prematurely trumpet the Phase II Trial results as positive and true was to tout the value of Peregrine and bavituximab in order to: (1) increase the amount of stock holdings each owned in the Company while the stock price was depressed; (2) make themselves invaluable to the Company; (3) make the Company dependent upon them to fix any problems they themselves caused; (4) induce partners to joint venture with Peregrine; (5) obtain operating loans to avoid dilution of Peregrine stock; (6) preserve their jobs and the value of their own personal Peregrine stock and options; (7) keep the Company afloat; and (8) survive to move into a Phase III clinical trial, all in the deliberately reckless hope that nothing amiss with the Phase II Trial data would be discovered and Peregrine could slide into a Phase III study.

B. Defendants Possessed The Information To Determine Who Received Bavituximab and Who Received Placebo After The Trial Was Unblinded in May 2012

285. As early as the unblinding of the Phase II Trial in May of 2012, Peregrine also possessed a test to detect the presence of HACA in a patient's blood who received bavituximab. *See, e.g.*, CW1 (¶ 124), CW3 (¶ 130), CW9 (¶ 166), CW10 (¶ 173, 175), CW20 (¶ 96). CW3, CW9, and CW10 stated that they were familiar with the HACA test used by Peregrine and CW3 and CW 10 stated that it had been conducted on patient blood samples many times during his tenure with Peregrine. *See* ¶¶ 130, 173, 175. A patient who had received placebo should not have any HACA in his or her blood sample as a person assigned to receive placebo should not have received bavituximab containing mouse DNA and thus no HACA should have been generated in his/her blood in response.

286. As early as the unblinding of the Phase II Trial in May of 2012, Peregrine had the ability to conduct P-K tests on blood samples of all of the 117 patients in the Phase II Trial and confirm using the now unblinded patient identification codes that those who were supposed to have received placebo did not in fact have bavituximab in their blood and to confirm that those who were supposed to have received bavituximab did in fact have bavituximab in their blood samples. *See, e.g.*, CW1 (¶¶ 123, 131); CW3 (¶¶ 135); CW9 (¶¶ 164, 167, 168, 169); CW10 (¶¶ 175, 181, 182, 183, 184, 187); CW11 (¶¶ 61, 63, 195, 196, 197, 198, 199, 201, 202); CW15 (¶ 103); CW17 (¶ 105).

PLAINTIFF'S CLASS ACTION ALLEGATIONS

287. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class consisting of all those who purchased or otherwise acquired Peregrine's securities between May 21, 2012 and September 26, 2012, inclusive, seeking to pursue remedies under the Exchange Act.

288. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class.

289. Record owners and other members of the Class may be identified from records maintained by Peregrine or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

290. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

291. Plaintiff will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

292. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts regarding the efficacy of bavituximab in treating second-line NSCLC cancer patients; and

(c) whether the members of the Class have sustained damages and, if so, the proper measure of damages.

293. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

Loss Causation

294. Defendant's wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

295. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and were deliberately reckless such that the market was deceived and by this course of conduct, the price of Peregrine securities was artificially inflated and this deliberately reckless course of conduct operated as a fraud or deceit on Class Period purchasers of Peregrine securities by misrepresenting the significance of the clinical data gathered as to the efficacy of bavituximab in treating second-line NSCLC cancer patients. Later, when Defendants' prior misrepresentations and material omissions became apparent to the market, the price of Peregrine securities fell precipitously, as the prior artificial inflation came out of

1 the price. As a result of their purchases of Peregrine securities during the Class
 2 Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*,
 3 damages, under the federal securities laws.

4 **Applicability of Presumption of Reliance:**

5 **Fraud-on-the-Market Doctrine**

6 296. At all relevant times, the market for Peregrine's securities was an
 7 efficient market for the following reasons, among others:

8 (a) Peregrine met the requirements for listing on the NASDAQ, a
 9 highly efficient and automated market;

10 (b) During the Class Period, on average, millions of shares were
 11 traded weekly, demonstrating a very active and broad market for Peregrine
 12 securities and permitting a strong presumption of an efficient market;

13 (c) As a regulated issuer, Peregrine filed periodic public reports with
 14 the SEC;

15 (d) Peregrine regularly communicated with public investors via
 16 established market communication mechanisms, including through regular
 17 disseminations of press releases on the national circuits of major newswire
 18 services and through other wide-ranging public disclosures, such as
 19 communications with the financial press and other similar reporting services;
 20 and

21 (e) Unexpected material news about Peregrine was rapidly reflected
 22 and incorporated into the Company's securities price during the Class Period.

23 297. As a result of the foregoing, the market for Peregrine's securities
 24 promptly digested current information regarding Peregrine from all publicly
 25 available sources and reflected such information in the price of Peregrine's
 26 securities. Under these circumstances, all purchasers of Peregrine's securities during
 27 the Class Period suffered similar injury through their purchase of Peregrine's
 28 securities at artificially inflated prices, and a presumption of reliance applies.

FIRST CLAIM

Violation of Section 10(b) Of

The Exchange Act and Rule 10(b)-5

Promulgated Thereunder Against All Defendants

298. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

299. This claim is brought against Peregrine and all of the Individual Defendants.

300. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (a) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (b) caused Plaintiff and other members of the Class to purchase Peregrine's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and/or reckless course of conduct, Defendants, and each of them, took the actions set forth herein.

301. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Peregrine's securities in violation of Section 10(b) of the Exchange Act and Rule 10(b)-5 thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

302. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and/or a reckless course of conduct as alleged herein in an effort to assure investors of Peregrine's value and performance and continued substantial growth,

1 which included the making of, or participation in the making of, untrue statements of
2 material facts and omitting to state material facts necessary in order to make the
3 statements made about Peregrine and its business operations and future prospects in
4 the light of the circumstances under which they were made, not misleading, as set
5 forth more particularly herein, and engaged in transactions, practices and/or a
6 reckless course of business that operated as a fraud and deceit upon the purchasers of
7 Peregrine's securities during the Class Period.

8 303. Each of the Individual Defendants' primary liability, and controlling
9 person liability, arises from the following facts: (a) the Individual Defendants were
10 high-level executives, directors, and/or agents at the Company during the Class
11 Period and members of the Company's management team or had control thereof; (b)
12 each of these defendants, by virtue of his responsibilities and activities as a senior
13 officer and/or director of the Company, was privy to and participated in the creation,
14 development and reporting of the Company's data from the Phase II Trial; (c) each
15 of these defendants enjoyed significant personal contact and familiarity with the
16 other defendants and was advised of and had access to other members of the
17 Company's management team, internal reports and other data and information about
18 the Company's Phase II Trial, finances and operations at all relevant times; and (d)
19 each of these Defendants was aware of the Company's dissemination of information
20 to the investing public which they knew or recklessly disregarded was materially
21 false and misleading.

22 304. Defendants had actual knowledge of the misrepresentations and
23 omissions of material facts set forth herein, or acted with reckless disregard for the
24 truth in that they failed to ascertain, verify and to disclose such facts, even though
25 such facts were available to them. As demonstrated by Defendants' false and
26 misleading statements issued throughout the Class Period, Defendants, if they did
27 not have actual knowledge of the omissions alleged, were deliberately reckless in
28 failing to obtain such knowledge by deliberately refraining from taking those steps

1 necessary to verify whether the clinical data reported regarding the Phase II Trial
2 was true and accurate or false and misleading.

3 305. As a result of the dissemination of the materially false and misleading
4 information and failure to verify and disclose material facts, as set forth above, the
5 market price of Peregrine's securities was artificially inflated during the Class
6 Period. In ignorance of the fact that market prices of Peregrine's securities were
7 artificially inflated, and relying directly or indirectly on the misleading statements
8 and Company press releases issued by Defendants, or upon the integrity of the
9 market in which the Company's securities trades, and/or on the absence of material
10 adverse information that was known to or recklessly disregarded by Defendants but
11 not disclosed in public statements by Defendants during the Class Period, Plaintiff
12 and the other members of the Class acquired Peregrine securities during the Class
13 Period at artificially high prices and were or will be damaged thereby.

14 306. At the time of said omissions and/or materially false and misleading
15 statements, Plaintiff and other members of the Class were ignorant of their
16 misleading nature, and believed them to be true. Had Plaintiff and the other
17 members of the Class and the marketplace known the truth regarding the clinical
18 data reported regarding Peregrine's Phase II Trial, Plaintiff and other members of
19 the Class would not have purchased or otherwise acquired their Peregrine securities,
20 or, if they had acquired such securities during the Class Period, they would not have
21 done so at the artificially inflated prices that they paid.

22 307. By virtue of the foregoing, Defendants have violated Section 10(b) of
23 the Exchange Act, and Rule 10b-5 promulgated thereunder.

24 308. As a direct and proximate result of Defendants' wrongful conduct,
25 Plaintiff and the other members of the Class suffered damages in connection with
26 their respective purchases and sales of the Company's securities during the Class
27 Period.
28

SECOND CLAIM

Violation of Section 20(a) Of

The Exchange Act Against The Individual Defendants'

309. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

310. The Individual Defendants acted as controlling persons of Peregrine within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, agency, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the misleading interim Phase II data filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements that Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to the clinical data gathered in the Phase II Trial, including the patient blood samples, which would have revealed the falsity of their prior public statements and/or would have enabled them to make truthful statements from the outset about the data gathered from the Phase II Trial, as well as Company's reports, press releases, public filings and other statements alleged by Plaintiff to have been false and misleading prior to and/or shortly after these statements were issued and thus had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

311. The Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: January 22, 2014

By:

Patrice L. Bishop
STULL, STULL & BRODY



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***Lead Counsel for Plaintiff and the Putative
Class***

PROOF OF SERVICE

STATE OF CALIFORNIA)
COUNTY OF LOS ANGELES } ss.:

I am employed in the county of Los Angeles, State of California, I am over the age of 18 and not a party to the within action; my business address is 9430 West Olympic Boulevard, 4th Floor, Beverly Hills, California 90212.

On January 22, 2014, I caused the following document(s) to be served:

SECOND AMENDED COMPLAINT

I served the above document(s) as follows:

By U.S. Mail. I enclosed the document(s) in a sealed envelope(s) or package(s) addressed to the persons at the addresses below and placed the envelope(s) for collection and mail, following our ordinary business practices. I am readily familiar with this firm's practice for collection and processing correspondence for mailing. On the same day that correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service, in a sealed envelope with postage fully prepaid.

I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Executed on January 22, 2014 at Beverly Hills, California 90212.

PAUL HARRIGAN
Type or Print Name


Signature

SERVICE LIST

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dmyers@rgrdlaw.com

**Counsel for Plaintiff Nathaniel L.
Anderson and the Tereshko
Investors Group**

CERTIFICATION OF NAMED PLAINTIFF

I, James T. Fahry ("Plaintiff") hereby retain Gainey & McKenna and such co-counsel as appropriate, subject to their investigation, to pursue my claims on a contingent fee basis and for counsel to advance the costs of the case, with no attorneys fee owing except as may be awarded by the court at the conclusion of the matter and paid out of any recovery obtained and I also hereby declare the following as to the claims asserted under the law that:

Plaintiff did not purchase the security that is the subject of this action at the direction of Plaintiff's counsel or in order to participate in this private action.

Plaintiff reviewed a copy of the complaint and is willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.

Plaintiff's transactions in *Peregrine Pharmaceuticals, Inc.* security that is subject of this action during the Class Period are as follows:

<u>No. of Shares</u>	<u>Stock Symbol</u>	<u>Buy/Sell</u>	<u>Date</u>	<u>Price Per Share</u>
<u>See Transactions sheet</u>				

Please list other transactions on a separate sheet of paper, if necessary.

Plaintiff has sought to serve as a class representative in the following cases within the last three years:

None.

Plaintiff will not accept any payment serving as a representative party on behalf of the class beyond Plaintiff's *pro rata* share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 13 day of November, 2012

James T. Fahry
Signature
James T. Fahry
Print Name (& Title if applicable)

Exhibit A to the James T. Fahey Certification

No. of Shares	Stock Symbol	Buy/Sell	Date	Price
20,000	PPHM	Buy	8/9/2012	\$2.08
20,000	PPHM	Buy	8/9/2012	\$2.08
5,000	PPHM	Buy	8/9/2012	\$2.19
24,000	PPHM	Buy	8/9/2012	\$2.22
27,300	PPHM	Buy	8/9/2012	\$2.23
2,700	PPHM	Buy	8/9/2012	\$2.22
4,686	PPHM	Buy	8/9/2012	\$2.28
15,314	PPHM	Buy	8/9/2012	\$2.25
20,000	PPHM	Buy	8/9/2012	\$2.27
100	PPHM	Buy	8/9/2012	\$2.28
9,900	PPHM	Buy	8/9/2012	\$2.29
20,000	PPHM	Buy	8/10/2012	\$2.36
10,000	PPHM	Buy	8/10/2012	\$2.36
5,677	PPHM	Buy	8/14/2002	\$3.48
200	PPHM	Buy	8/14/2012	\$3.45
400	PPHM	Buy	8/14/2012	\$3.38
3,700	PPHM	Buy	8/14/2012	\$3.33
23	PPHM	Buy	8/14/2012	\$3.28
7,600	PPHM	Buy	8/14/2012	\$3.30
400	PPHM	Buy	8/14/2012	\$3.29
2,000	PPHM	Buy	8/14/2012	\$3.26
13,850	PPHM	Buy	8/14/2012	\$2.54
6,150	PPHM	Buy	8/14/2012	\$2.53
3,000	PPHM	Buy	8/14/2012	\$2.54
2,652	PPHM	Buy	8/14/2012	\$2.56
14,400	PPHM	Buy	8/14/2012	\$2.55
9,948	PPHM	Buy	8/14/2012	\$2.57
20,000	PPHM	Buy	8/14/2012	\$2.45
12,450	PPHM	Buy	8/14/2012	\$2.45
4,400	PPHM	Buy	8/14/2012	\$2.45
100	PPHM	Buy	8/14/2012	\$2.45
3,050	PPHM	Buy	8/14/2012	\$2.50
10,000	PPHM	Buy	8/14/2012	\$2.50
22,400	PPHM	Buy	8/14/2012	\$2.50
7,500	PPHM	Buy	8/14/2012	\$2.50
100	PPHM	Buy	8/14/2012	\$2.50
19,500	PPHM	Buy	8/14/2012	\$2.50
10,400	PPHM	Buy	8/14/2012	\$2.50
100	PPHM	Buy	8/14/2012	\$2.50
5,200	PPHM	Buy	8/14/2012	\$2.53
4,800	PPHM	Buy	8/14/2012	\$2.53

10,000	PPHM	Buy	8/14/2012	\$2.54
10,000	PPHM	Buy	8/14/2012	\$2.55
10,000	PPHM	Buy	8/14/2012	\$2.59
10,000	PPHM	Buy	8/14/2012	\$2.59
4,600	PPHM	Buy	8/14/2012	\$2.58
800	PPHM	Buy	8/14/2012	\$2.58
200	PPHM	Buy	8/14/2012	\$2.58
4,050	PPHM	Buy	8/14/2012	\$2.59
350	PPHM	Buy	8/14/2012	\$2.59
10,000	PPHM	Buy	8/14/2012	\$2.63
5,000	PPHM	Buy	8/20/2012	\$2.85
5,000	PPHM	Buy	8/20/2012	\$2.86
20,000	PPHM	Sell	8/14/2012	\$2.62
5,000	PPHM	Sell	8/14/2012	\$2.63
5,000	PPHM	Sell	8/14/2012	\$2.59
100	PPHM	Sell	8/14/2012	\$2.60
100	PPHM	Sell	8/14/2012	\$2.59
7,201	PPHM	Sell	8/14/2012	\$2.59
10,000	PPHM	Sell	8/14/2012	\$2.52
4,700	PPHM	Sell	8/14/2012	\$2.56
5300	PPHM	Sell	8/14/2012	\$2.55
10000	PPHM	Sell	8/14/2012	\$2.50
4150	PPHM	Sell	8/14/2012	\$2.50
3600	PPHM	Sell	8/14/2012	\$2.48
2,250	PPHM	Sell	8/14/2012	\$2.48
10000	PPHM	Sell	8/14/2012	\$2.49
100	PPHM	Sell	8/14/2012	\$2.48
100	PPHM	Sell	8/14/2012	\$2.48
9800	PPHM	Sell	8/14/2012	\$2.48
10000	PPHM	Sell	8/14/2012	\$2.49
300	PPHM	Sell	8/14/2012	\$2.55
3700	PPHM	Sell	8/14/2012	\$2.54
10000	PPHM	Sell	8/14/2012	\$2.52
10000	PPHM	Sell	8/14/2012	\$2.53
10000	PPHM	Sell	8/14/2012	\$2.53
6000	PPHM	Sell	8/14/2012	\$2.52
10000	PPHM	Sell	8/14/2012	\$2.51
200	PPHM	Sell	8/14/2012	\$2.52
100	PPHM	Sell	8/14/2012	\$2.51
6850	PPHM	Sell	8/14/2012	\$2.51
100	PPHM	Sell	8/14/2012	\$2.50
100	PPHM	Sell	8/14/2012	\$2.50
19800	PPHM	Sell	8/14/2012	\$2.50

Exhibit A to the James T. Fahey Certification

10,000	PPHM	Sell	8/14/2012	\$2.50
2850	PPHM	Sell	8/14/2012	\$2.50
20,000	PPHM	Sell	8/14/2012	\$2.50
100	PPHM	Sell	8/23/2012	\$2.36
1500	PPHM	Sell	8/23/2012	\$2.36
3400	PPHM	Sell	8/23/2012	\$2.36
5000	PPHM	Sell	8/23/2012	\$2.36
2300	PPHM	Sell	8/23/2012	\$2.40
2700	PPHM	Sell	8/23/2012	\$2.40
4500	PPHM	Sell	8/23/2012	\$2.41
35	PPHM	Sell	8/23/2012	\$2.41
3064	PPHM	Sell	8/23/2012	\$2.40
2600	PPHM	Sell	8/23/2012	\$2.40
7,400	PPHM	Sell	8/27/2012	\$1.97
19,050	PPHM	Sell	8/27/2012	\$1.97
950	PPHM	Sell	8/27/2012	\$1.96
20,000	PPHM	Sell	8/27/2012	\$1.96
50	PPHM	Sell	8/27/2012	\$1.95
11430	PPHM	Sell	8/27/2012	\$1.94
10000	PPHM	Sell	8/27/2012	\$1.86
7154	PPHM	Sell	8/27/2012	\$1.89
12846	PPHM	Sell	8/27/2012	\$1.88
3800	PPHM	Sell	8/27/2012	\$1.88
5900	PPHM	Sell	8/27/2012	\$1.88
2300	PPHM	Sell	8/27/2012	\$1.84
8000	PPHM	Sell	8/27/2012	\$1.84
20000	PPHM	Sell	8/27/2012	\$1.85
700	PPHM	Sell	8/27/2012	\$1.86
17820	PPHM	Sell	8/27/2012	\$1.85
2788	PPHM	Sell	8/27/2012	\$1.88
17212	PPHM	Sell	8/27/2012	\$1.87
2100	PPHM	Sell	8/27/2012	\$1.90
5952	PPHM	Sell	8/27/2012	\$1.89
3900	PPHM	Sell	8/27/2012	\$1.88
8048	PPHM	Sell	8/27/2012	\$1.88
400	PPHM	Sell	8/27/2012	\$1.90
400	PPHM	Sell	8/27/2012	\$1.89
100	PPHM	Sell	8/27/2012	\$1.89
9100	PPHM	Sell	8/27/2012	\$1.89
<u>Date Purchased</u>	<u>Calls Purchased</u>	<u>Strike Price</u>	<u>Price Paid</u>	
8/9/2012	200	01/19/13 \$2.5	\$0.60	

8/9/2012	23	01/19/13 \$2.5	\$0.60
8/9/2012	100	01/19/13 \$2.5	\$0.70
8/9/2012	300	01/19/13 \$2.5	\$0.75
8/9/2012	100	01/19/13 \$2.5	\$0.75
8/9/2012	300	01/19/13 \$2.5	\$0.90
8/9/2012	200	01/19/13 \$2.5	\$0.90
8/9/2012	77	01/19/13 \$2.5	\$0.90
8/9/2012	400	01/19/13 \$2.5	\$0.90
8/9/2012	50	10/20/12 \$2.5	\$0.55
8/9/2012	50	10/20/12 \$2.5	\$0.60
8/9/2012	100	10/20/12 \$2.5	\$0.60
8/9/2012	100	10/20/12 \$2.5	\$0.60
8/9/2012	100	10/20/12 \$2.5	\$0.70
8/27/2012	100	01/19/13 \$2.5	\$0.55
8/27/2012	100	01/19/13 \$2.5	\$0.55
8/27/2012	100	01/19/13 \$2.5	\$0.55
8/27/2012	100	01/19/13 \$2.5	\$0.55
8/27/2012	100	01/19/13 \$2.5	\$0.55
8/27/2012	179	01/19/13 \$2.5	\$0.60
8/27/2012	21	01/19/13 \$2.5	\$0.55
8/27/2012	50	01/19/13 \$2.5	\$0.55
8/27/2012	150	01/19/13 \$2.5	\$0.60
8/27/2012	300	01/19/13 \$2.5	\$0.65
8/27/2012	300	01/19/13 \$2.5	\$0.60
8/27/2012	200	01/19/13 \$2.5	\$0.60
8/27/2012	200	01/19/13 \$2.5	\$0.60
8/27/2012	200	01/19/13 \$2.5	\$0.60
8/27/2012	120	01/19/13 \$2.5	\$0.60
8/27/2012	180	01/19/13 \$2.5	\$0.65
8/27/2012	100	01/19/13 \$2.5	\$0.65
8/27/2012	200	01/19/13 \$2.5	\$0.65
8/27/2012	100	01/19/13 \$2.5	\$0.65
8/27/2012	100	01/19/13 \$2.5	\$0.65
8/27/2012	100	01/19/13 \$2.5	\$0.65
8/27/2012	200	01/19/13 \$2.5	\$0.70
8/27/2012	200	01/19/13 \$2.5	\$0.70
8/27/2012	100	01/19/13 \$2.5	\$0.70
8/27/2012	100	01/19/13 \$2.5	\$0.70
8/27/2012	100	01/19/13 \$2.5	\$0.70
9/5/2012	20	01/19/13 \$2.5	\$1.00
9/5/2012	10	01/19/13 \$2.5	\$1.00
9/7/2012	200	01/19/13 \$5.0	\$1.00
9/7/2012	270	01/19/13 \$2.5	\$2.25

Exhibit A to the James T. Fahey Certification

<u>Date Sold</u>	<u>Calls Sold</u>	<u>Strike Price</u>	<u>Price Paid</u>
9/18/2012	50	01/19/13 \$5.0	\$0.70
9/18/2012	10	01/19/13 \$5.0	\$0.90
9/20/2012	140	01/19/13 \$5.0	\$1.30
9/20/2012	124	01/19/13 \$5.0	\$1.25
9/20/2012	76	01/19/13 \$5.0	\$1.30
9/20/2012	200	01/19/13 \$5.0	\$1.30
9/20/2012	300	01/19/13 \$5.0	\$1.30
9/20/2012	50	01/19/13 \$5.0	\$1.20
9/20/2012	150	01/19/13 \$5.0	\$1.25
9/20/2012	100	01/19/13 \$5.0	\$1.25
9/20/2012	200	01/19/13 \$5.0	\$1.25
9/20/2012	350	01/19/13 \$5.0	\$1.25
9/20/2012	40	01/19/13 \$5.0	\$1.25
9/20/2012	110	01/19/13 \$5.0	\$1.25
9/20/2012	50	01/19/13 \$5.0	\$1.35
9/20/2012	150	01/19/13 \$5.0	\$1.35
9/20/2012	200	01/19/13 \$5.0	\$1.40
9/25/2012	45	01/19/13 \$1.0	\$0.95